AccelStim™

Bone Healing Therapy

Instruction Manual

Model 4300

ORTHOFIX®

Symbol		Meaning
REF	ISO 15223-1 5.1.6	**Catalogue number:** This symbol specifies the catalogue number so that the medical device can be identified.
SN	ISO 15223-1 5.1.7	**Serial number:** This symbol specifies the medical device serial number.
	IEC 60601-1 ISO 7010-M002	**Read instructions for use:** Failure to read the instructions may result in a hazard.
	IEC 60417 5333	**Type BF applied part:** Applied part (ultrasound transducer) isolated from the rest of the appliance with a specific degree of protection against electrical hazards, specifically regards admissible leakage current.
	ISO 15223-1 5.4.12	**Single patient multiple use:** Indicates a medical device that may be used multiple times (multiple procedures) on a single patient
	IEC 60417 5172	**Class II equipment:** Appliance in which protection against electric shock does not rely on basic insulation only, but includes additional safety precautions such as double insulation.
	ISO 15223-1 5.1.1	**Manufacturer:** Name and address of the manufacturer.
	ISO 15223-1 5.1.3	**Date of Manufacture**
	Directive 2012/19/EU	**Not for general waste:** This symbol indicates that the AccelStim device 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 sales representative.
	ISO 15223-1 5.3.7	**Temperature limits**
	ISO 15223-1 5.3.9	**Atmospheric pressure limitation**
	ISO 15223-1 5.3.8	**Humidity limitation**
	ISO 15223-1 5.3.4	**Keep dry** **IP22:** Degrees of protection provided by enclosures, see page 24.
℞ ONLY	21 CFR 801.109	**Prescription only**
	ASTM F2503	**MR Unsafe:** Device must not be subjected to MRI scans.
	ISO 15223-1 5.1.4	**Use-by Date**
	ISO 15223-1 5.2.7	**Non Sterile**

MEDICAL-ULTRASOUND EQUIPMENT
AS TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARD ONLY IN ACCORDANCE WITH
ANSI/AAMI ES60601-1(2005) + AMD 1 (2012)
CAN/CSA-C22.2 N0.60601-1:14

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Orthofix Patient Services: 800-535-4492 or 214-937-2718
To learn more about Orthofix, please visit our website at www.orthofix.com.

PRESCRIPTION INFORMATION

Indications for Use

The AccelStim™ device is indicated for the noninvasive treatment of established nonunions excluding skull and vertebra, and for accelerating the time to a healed fracture for fresh, closed, posteriorly displaced distal radius fractures and fresh, closed or Grade I open tibial diaphysis fractures in skeletally mature adult individuals when these fractures are orthopedically managed by closed reduction and cast immobilization.

Contraindications

There are no known contraindications for the AccelStim device.

DEVICE DESCRIPTION

The AccelStim device is a medical device that applies ultrasound to the treated area to accelerate the osteogenic process, thereby reducing healing times. The AccelStim device generates a low-intensity pulsed ultrasound (LIPUS) signal as a prescribed, nonsurgical treatment for nonunion fractures or fresh fractures (closed, posteriorly displaced distal radius fractures, or closed or Grade I open tibial diaphysis fractures). The ultrasound signal is an acoustic vibration with frequency above the human auditory level, thus the device is silent. To learn more about bone growth stimulation, please visit our patient website at BoneGrowthTherapy.com.

The device is lightweight, adjustable and portable. Treatment application is simple and does not require any assistance by specialized medical staff as the patient can apply it on their own. Everything needed for the treatment of your fracture is included in each device box (Figure1: The AccelStim device box contents).

Figure 1: The AccelStim device box contents

Device Components

Model 4300

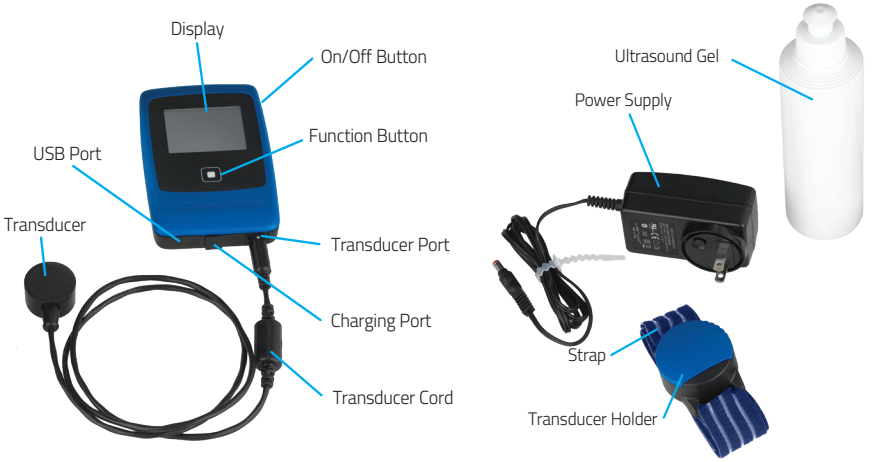


Figure 2: AccelStim device components

Generator (See Figure 3)

The generator is equipped with:

- A liquid crystal display (LCD) and audible indicators provide important feedback during treatment.
  1. The battery charge status
  2. The daily treatment timer
  3. The lowest part of the screen will display all symbols related to the execution of the treatment and error messages
- Three buttons
  4. Function button to start or pause the treatment
  5. ON/OFF button, marked with ⏻ symbol
  6. RESET button
- On the lower side of the device, there are three sockets:
  7. The USB port marked with symbol
  8. The charging port marked with symbol
  9. The transducer port marked with symbol

Figure 3 : The AccelStim device Generator

Ultrasound Transducer

Figure 4 : Transducer and Transducer Cord

The transducer (with the writing upward facing) should be placed inside the transducer holder which is connected to the strap (as seen in Figure 5). The transducer holder must be placed directly over the treatment area.

Figure 5 : Transducer inside the Transducer Holder

Ultrasound Gel

The supplied ultrasound gel is provided for use with the AccelStim device. Gel is necessary to allow the ultrasound signal to reach your fracture through the skin. The gel must be applied to the transducer, side with no writing, before starting a treatment. Apply a thick layer (1-2mm) of gel to the transducer as the AccelStim device will not work properly if the gel is not covering the transducer. If you need more gel, please contact Patient Services at 1-800-535-4492.

NOTE: Some patients may experience mild 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.

Power Supply (Charger)

The AccelStim device is powered by a rechargeable lithium-ion battery pack. The battery pack may provide up to five 20-minute treatments when fully charged. An external power supply to charge the battery is provided with the device. Use only the Orthofix provided power supply to charge the battery. Read more about charging the device in the Battery and Charging Safety section.

Figure 6 : Power Supply (Charger)

Device Life and Usage

The AccelStim device should be worn for 20 minutes each day (as prescribed by your physician) and it's recommended to treat at the same time each day. Your physician will determine the overall length of treatment (months/weeks) on an individual basis according to fracture healing progress. The AccelStim device provides daily treatments for up to 365 days.

The expiration date for the device can be found on the external packaging label. This device should only be used by one patient before disposal. For instructions on how to dispose of this device, see the Recycle or Disposal of Your Device after Use section in the manual on page 18.

Warnings

The safety and effectiveness of the use of this device 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 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, anticoagulant, and prescription nonsteroidal anti-inflammatory medications

- 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.
- Nonunions of the vertebra and the skull.
- Individuals lacking skeletal maturity.
- Fresh 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 lower leg).
- Fresh fractures 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 bones in place), or that are not sufficiently stable for closed reduction and cast immobilization (manipulation of the fracture without surgery).
- Clinical studies leveraged to support the safety and effectiveness of the AccelStim device may not necessarily be applicable to patients of all races and ethnicities. Such demographic details were not provided in the referenced clinical studies.
- The AccelStim device is MR Unsafe. The device presents a projectile hazard in this environment. 

- The device should not be used over skin that is infected or is not intact, if scarring or blood is evident at the application point, or in the presence of other local substances or abnormal tissues that may affect the acoustic signal such as inflammation (rash), hematoma, or abscess. The impact of such soft tissue abnormalities within the effective radiating area of the transducer has not been studied by any manufacturer.

Precautions

- The AccelStim device 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 the AccelStim device. The physician should advise the patient, or other person in close proximity during treatment, to be evaluated by their attending cardiologist or implant physician before starting treatment with the AccelStim device.
- The cords pose a risk for strangulation. Keep out of reach of children.
- Cell phones, televisions, and other devices using radio frequency identification (RFID) readers, electronic security systems (e.g., metal detectors, electronic article surveillance), near-field communications (NFC) systems, wireless power transfer and unique medical emitters such as electrocautery, electrosurgical units, and diathermy equipment may cause interference. Don't use the AccelStim device closer than 30 cm (12 inches) from these electromagnetic (EM) emitters.
- The safety and effectiveness of the AccelStim device for use of more than one daily 20-minute treatment period has not been studied.
- 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 result in the transducer being only partially coupled to the skin. This may reduce the effectiveness of the AccelStim device in treating the fracture.

- Only the region of the fracture within the effective radiating area (3.5 cm2) of the transducer is likely to benefit from the AccelStim device's treatment. Therefore, the physician and patient should take care in appropriately placing of the device over the fracture site.
- Placement of the transducer directly over internal fixation may result in the treatment signal being partially or fully blocked and may reduce the effectiveness of the AccelStim device in treating the fracture.
- When choosing a treatment site, the transducer shall be positioned such that the ultrasound beam is not impeded by any internal fixation which is directly in line with the fracture site (i.e., not directly over metal plating). This may require placement of the transducer on the opposite side of the limb or perpendicular to the fracture line. Correct placement should be confirmed using radiographic and/or anatomical markers by a health care provider during the fitting of the device. The AccelStim device's site of application should be marked onto the patient's skin with an indelible marker to guide future transducer placements.

Adverse Events

Unlike conventional (physical therapy) ultrasound devices, the AccelStim device is incapable of producing harmful temperature increases in body tissue.[26] The output intensity of the device is 30mW/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 (cavitation). While no device-related adverse reactions or medical complications were reported in the referenced clinical studies (see "Clinical Studies" section in this manual), there are several potential adverse events associated with the use of this device. In case you experience any pain, discomfort or other unwanted effects related to the use of the device, stop using the device and contact Patient Services and/or your physician.

DEVICE OPERATION

The AccelStim device can be powered in two modes:

- Using internal battery mode. When the internal battery is fully charged, the AccelStim device can deliver up to five treatments.
- Using the external power supply, the unit is powered while recharging the internal battery.

NOTE: The battery must be fully charged before using the device for the first time.

Performing a Treatment

Step-by-step instructions for device application can be found in the table below.

To Apply

The AccelStim device, gel, transducer, transducer holder, and strap will be needed to treat your fracture. The strap is not needed if you are in a cast for your fracture. If your physician has placed an 'X' on the fracture site this is the spot that the transducer holder and transducer will need to be placed directly over.

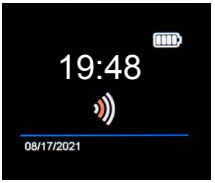
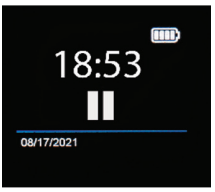
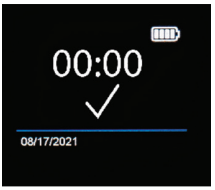
Check the transducer and the transducer cord before starting treatment. If there are any signs of damage (cracks, etc.) do not use the AccelStim device and contact Patient Services at 1-800-535-4492.

PRECAUTION: This AccelStim device is nonsterile and does not require sterilization before use. Placement on an open wound is not advised.

	1. Connect the transducer to the AccelStim device by inserting the transducer cord into the transducer port. Keep the white dot on the connector over-mold facing upwards.
	2. Open the blue cover of the transducer holder by rotating it counterclockwise. 3. Place the transducer holder over the area that will receive treatment and secure with the Velcro attached to the elastic strap. The strap should be snug, comfortable, and against the skin to prevent motion or slippage. Do not overtighten the strap. Excess strap can be cut if needed to adjust the transducer holder over the fracture site.
	4. Apply the gel to the side of the transducer with no writing to form a 1-2 mm thick layer. Use a finger to spread the gel on the transducer to obtain an even layer.

	5. Insert the transducer inside the transducer holder so that the serial number is visible. 6. Close the blue cover by rotating it clockwise.

Starting a Treatment

	1. Turn on the device by pressing the on/off button for two seconds. Once you hear a beep, release the button, and the display screen will light up.
	2. The Orthofix logo will appear on the display screen as the device powers on.
	3. The device will display 20 minutes of treatment time along with a play symbol to specify that the device is now ready for treatment. The gel symbol will flash for 10 seconds to remind the user to apply the ultrasound gel on the transducer before starting treatment.
	4. To start the treatment, press the function button on the front panel of the device. The AccelStim device signals the start of treatment with a beep. During treatment, the display shows the remaining therapy time. **NOTE:** The AccelStim device will power down automatically after two minutes of inactivity, to reduce battery consumption.
	5. To pause the device in the middle of a treatment, press the function button and the treatment will stop. The display will show a pause symbol with the remaining treatment time stopped. To resume treatment, press the function button again
	6. Once the treatment screen reaches zero, the display screen will show a checkmark to specify treatment completed and emit three beeps. After 30 seconds, the AccelStim device will automatically turn off.

Care and Cleaning After Treatment Completed

The AccelStim device should be used following good hygiene practices and cleaned regularly. Avoid hair, dust, and exposure to direct sunlight. Before cleaning the AccelStim device, make sure that it is switched off and disconnected from the power supply. To avoid potential damage, handle the transducer carefully using the instructions below, and do not drop it. Clean the device thoroughly to help ensure effective treatment.

Clean the device after each treatment as indicated below:

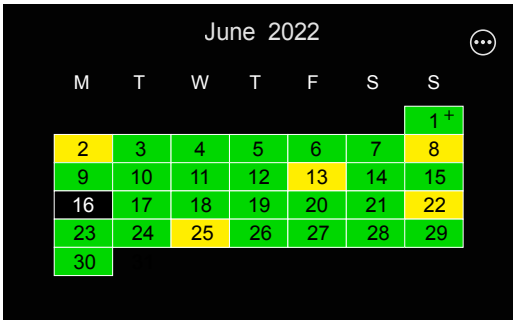
	1. Turn off the AccelStim device by press and hold down the On/Off button until hear a short beep.
	2. Open the blue cover of the transducer holder by rotating it counterclockwise. 3. Gently remove the transducer from the transducer holder.
	4. Gently clean the transducer with a slightly damp cloth using water or a neutral detergent (such as household liquid dishwashing detergent).
	5. Clean off any ultrasound gel from the transducer holder, strap or your skin.

CAUTION:

- Never use any spray products directly on the AccelStim device to avoid the risk of liquid penetration.
- Never pour water or liquids of any type onto the AccelStim device.
- The elastic strap is a washable fabric like ordinary clothing.

Tracking Your Treatment

The AccelStim device tracks your overall compliance to the treatments performed for up to 365 days. Up to 104 recent treatment sessions are visible on the AccelStim device while in Calendar Mode. Both the treatment day and the duration of the treatment are recorded and displayed as follows:

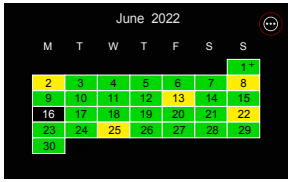


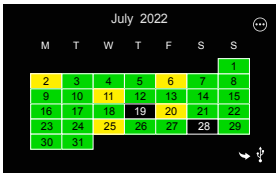
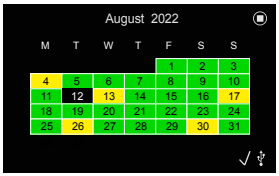
- Day/Date on black background, no treatment performed.
- Day/Date on yellow background, less than 20 minutes treatment performed.
- Day/Date on green background, 20 minutes treatment performed.
- Day/Date on green background and along with a + symbol, more than one 20 minute treatment performed.

NOTE: The AccelStim device will display compliance data for up to 104 treatment records. The complete record is available by download via USB – reference under section "How to Export Your Treatment History Data."

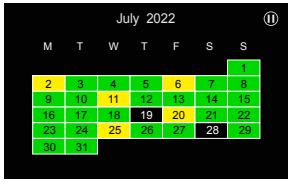
To Enter Calendar Mode

To view your treatment summary history perform the following steps to enter calendar mode:

	1. To enter calendar mode the AccelStim device should be off or while device is charging. 2. Press and hold the On/Off button for at least 5 seconds until you hear a long beep.
	3. The display screen will show the first treatment calendar month that compliance data was recorded. 4. In the upper right corner, there will be an image of three small dots. The three small dots are displayed to indicate that the other months of treatment history will be shown on the display screen.

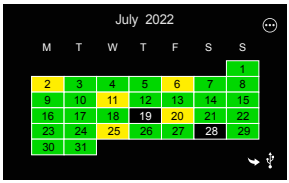
	5. After 5 seconds, the display screen will automatically switch calendar months to show the treatment history captured the following month.
	6. The sequence will stop once the last calendar month of treatment history was recorded. In the upper right corner, a stop symbol will display. Pressing the function button again, will restart the treatment summary history from the beginning. 7. To exit calendar mode, and turn off the AccelStim device, press and hold the on/off button until you hear a short beep.

Pausing Your Treatment Summary History

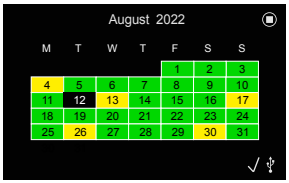
	1. Press the function button to pause the sequence of treatment history from month to month. Pausing the sequence allows you to view your treatment history longer than 5 seconds.
	2. Pressing the function button to pause the sequence will display a pause symbol in the upper right corner. Pressing the function button again will restart the sequence.

How to Export Your Treatment History Data

To export your treatment history you will need a portable USB storage device. In order to do this, please use the following steps:



1. Insert a portable USB storage into the USB port.
2. Turn on the AccelStim device in calendar mode, as specified in "To Enter Calendar Mode".
3. The USB symbol appears on the bottom right corner along with an arrow symbol indicating data has been saved on the portable USB storage device, in the file labeled "AccelStimTrtLog_ nnnnnnnnn.txt", where "nnnnnnnnn" is the serial number of the device. If the file already exists on the portable USB storage device, data will be overwritten.



4. After five seconds, the next month is displayed and data is appended to the same file on the portable storage device; this step is repeated for each displayed month.
5. Data saving ends when the display shows the last month of the registered treatments and the check symbol ✓ is shown next to the symbol.
6. Remove the portable USB storage device and analyze the data with a PC. In the case of Excel, please use the function "import data from the file."

The AccelStim device stores the overall treatment record and up to 104 detailed treatment records which include the treatment day and duration of the treatment. Detailed treatment data (day and duration of treatment) prior to the identified 104 treatment records is not accessible once the day has passed. If you want this type of data for the entire life of the device, it is recommended that you export your treatment history approximately every 3 months.

NOTE: In the event the function button is pressed and restarts the treatment summary history sequence while the portable USB storage device is still connected to the AccelStim device, the treatment data file will be overwritten.

If the portable USB storage device is not removed and the AccelStim device is turned on in treatment mode, the connection of the portable USB storage device is indicated by the symbol next to the battery symbol. When the portable USB storage device is removed from the AccelStim device, the symbol disappears.

Device Use and Care

The AccelStim device should be handled with care. Follow these instructions to ensure optimal and safe operation of the device.

- The AccelStim device is for single patient use.
- Inspect the device prior to each use for wear, deterioration or damage.
- The use of accessories other than those specified and provided may result in increased emissions or decreased immunity of the device.
- Dropping or mishandling the AccelStim device may damage the device and it may stop working.
- The patient is the intended operator of this device; for safety purposes all instructions should be followed when using the AccelStim device.
- Use of the AccelStim device in any manner other than intended could have harmful effects and/or void the warranty.
- If any parts of the AccelStim device or accessories are damaged, do not use the AccelStim device. Please contact Patient Services at 1-800-535-4492.
- Do not attempt to modify, disassemble or repair the AccelStim device. There are no user serviceable parts inside.
- Check the integrity of the transducer before each treatment session. If it is damaged, contact Patient Services at 1-800-535-4492 for a replacement.
- Do not expose the AccelStim device or its lithium-ion battery to heat sources or throw into a fire due to risk of malfunction or explosion.
- Do not use the device or its applied parts (transducer) near breathing systems or other devices that use concentrated oxygen.
- Do not handle any of the system components with wet hands, especially when connecting the power supply.
- Do not dip or splash any of the system's components with water or any other type of liquid. In the event of the accidental immersion of the AccelStim device in liquids, it must no longer be used. Contact Patient Services at 1-800-535-4492 if any of these occur.
- The AccelStim device is designed to alert the user of any problems by means of visual and audio messages. When possible, restore the normal condition and restart the treatment as described within the Troubleshooting the AccelStim device section of this user manual on page 20.
- Do not connect any part of the unit to other equipment or devices.
- Do not connect the AccelStim device to any part not intended for use and not supplied by the manufacturer.
- Attention: connecting cables could cause a strangulation hazard if incorrectly used.
- Do not put any part of the medical device into mouth in order to avoid risk of suffocation.
- Do not cover the device during charging or use.
- Avoid placing the control unit against the skin/body while charging the battery as the unit may become hot.
- The user must never make any repairs on the system.
- In case of failure, the user should contact Patient Services at 1-800-535-4492.
- Device Interference: Electromagnetic interference, such as active cellular phones, radio-frequency identification (RFID) readers, electronic security systems (e.g., metal detectors, electronic article surveillance), near-field communications (NFC) systems, wireless power transfer and unique medical emitters such as electrocautery, electrosurgical units, and diathermy equipment can interfere

with the normal AccelStim device operation. To restore normal operation, press the reset button on the left side of the AccelStim device with a pointed object, and turn on the device. Be sure to remove the source of disturbance before continuing the treatment if closer than 30 cm (12 inches).

Battery and Charging Safety

To ensure that the device is functioning properly, the AccelStim device constantly monitors battery voltage level in treatment mode and displays on the upper right corner of the screen. When the battery level decreases to low battery level, the plug symbol and the battery level shown in red indicate the need to connect the external power supply to recharge the battery. In the low battery condition, treatment delivery can continue.

If not recharged, the battery level decreases to an empty battery level, indicated by a flashing empty battery symbol and three repeated short beeps. The AccelStim device will automatically stop treatment. To continue treatment, connect the power supply and press the function button.

Recharging the AccelStim device Battery

To recharge the battery within the AccelStim device, use the following steps:

	1. Open the charging port cover on the generator. 2. Plug the power supply DC plug into the charging port located on the generator.
	3. Plug the power supply into an AC wall outlet. 4. When the power is connected, the generator emits a short "beep" and the battery charging process started. During the recharging battery process, the battery charge status indicator moves from one level to the next until process is finished. Please refer to Visual and Audio Battery Indicators on page 20 for more information. 5. When the charging process is completed the full battery symbol is displayed on the screen. Remove the power supply and insert the rubber piece back into the charging port.

NOTE: When the power supply is connected to the AccelStim device while the device is in treatment mode, the charging process starts and a flash symbol appears next to the battery status symbol.

WARNING: In case of a faulty power supply, the device is not powered on or charging is not started, contact Patient Services at 1-800-535-4492 for assistance.

Travel
Check with your airline regarding recommendations for packing and traveling with the AccelStim device. The device contains rechargeable lithium ion batteries that are not serviceable or removable.

Recycle or Disposal of Your Device After Use
The AccelStim device and all its parts cannot be disposed of as urban waste but are subject to separate collection according to the procedures established by local authorities.

To help reduce waste from going to the landfill, Orthofix is happy to help you recycle your AccelStim device after your treatment is complete and your physician has advised you to discontinue use.

Please visit BoneGrowthTherapy.com/Recycle or contact Patient Care Services at 1-800- 535-4492 for further information on our free recycling program. We'll provide you with a pre-paid return mailing label so that your device can be recycled.

If you choose not to recycle your AccelStim device, you may dispose of the device according to your local governing guidelines (ordinances). We strongly encourage you to take advantage of our free recycling program, so we can work together and limit waste. Let's make a difference together!

The AccelStim device is a US Class III medical device (prescription only) that cannot be sanitized or used by another person.

Dispose of the device properly to prevent injury.
DO NOT dispose of the AccelStim device in an incinerator.
This device contains lithium batteries.

SERVICE

If you have questions concerning the device or require any assistance, please call Patient Services at 1-800-535-4492 (U.S. only). There are no user serviceable parts.

WARRANTY

Orthofix US LLC ("Orthofix") warrants the AccelStim device to be free from defects in materials and workmanship for one year from the date of first use. Provided that all terms and conditions of this Limited Warranty are complied with, Orthofix will replace defective components.

This Limited Warranty applies to the product only under normal use and does not cover any damage or defect caused by accident, misuse, abuse, fire, flood, and acts of God, or by any alteration, tampering, repair, or attempted repair by anyone other than Orthofix. This warranty only applies to the patient for whom the product is prescribed and is not assignable or transferable.

Defective products covered by this Limited Warranty must be returned to Orthofix, Attention: Orthofix Returns. You must call a Patient Services representative at 1-800-535-4492 or your local distributor to obtain the return authorization number and address prior to returning the product.

Except as specifically required by applicable law, the foregoing warranty is in lieu of all other warranties, expressed or implied. Orthofix specifically disclaims any and all warranties of merchantability or fitness for a particular purpose. Under no circumstances shall Orthofix, its authorized representative, affiliated, or subsidiary companies be liable for special, consequential, or incidental damages. The sole remedy with respect to any defective product shall be limited to replacement.

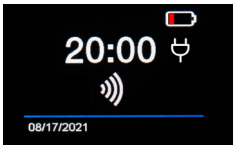
This Limited Warranty may not be extended or modified except in writing by Orthofix. No sales person, representative, distributor or physician is authorized to make or consent to any extension or modification of the terms of this Limited Warranty.

For additional information and/or device assistance, contact Orthofix Patient Services at 1-800-535-4492.

TROUBLESHOOTING THE ACCELSTIM DEVICE

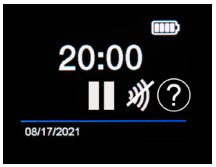
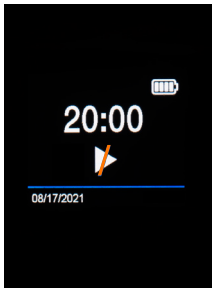
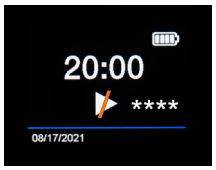
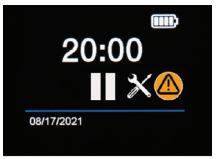
The AccelStim device will disrupt operation if alarm conditions occur. You will be notified by visual sounds and/or audio messages described in this section. If further technical assistance is required, please contact Patient Services at 1-800-535-4492.

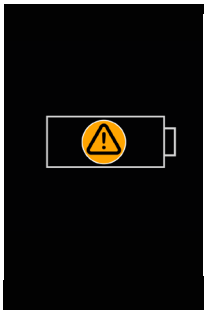
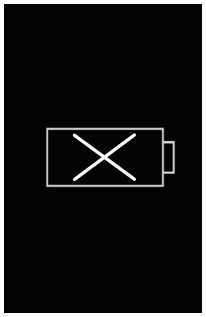
Visual and Audio Battery Indicators

	Battery charge status is shown on the upper right corner of the display. When the battery is fully charged, the AccelStim device can deliver up to five treatments.
	The battery symbol is characterized by several notches, which decrease as the battery runs down.
	The battery level will decrease gradually until it reaches the low battery level. The red indicator and the plug symbol will display indicating the need to connect the power supply to recharge the battery. When the battery level is low, connect to the power supply using the instructions on page 16.
	When the power supply is connected to the AccelStim device, the charging process starts and a flash symbol appears next to the battery status symbol. **WARNING:** In case of a faulty power supply, the flash symbol does not appear. Contact Patient Services for assistance.
	***Charge & Treat Mode:*** During the battery charging process, the battery charge status indicator moves from one level to the next until the process is finished. When the charging process is completed the full battery symbol is displayed.
	***Charge Only Mode:*** It is possible to recharge the battery when the AccelStim device is turned off.
	If a faulty battery is detected when the device is turned on and the charging process is not possible, a battery symbol with the warning symbol (triangle/exclamation point) will appear on the screen. Please contact Patient Services at 1-800-535-4492 for assistance.
	In case of faulty battery, it is possible to complete a treatment by connecting the external power supply to the AccelStim device. After a few seconds, the AccelStim device will automatically start in treatment mode. At the end of the treatment, it is necessary to disconnect the power supply from the AccelStim device to power down the device. In case of faulty battery, it is not possible to switch the AccelStim device to calendar mode. Battery charge status is shown on the upper right corner of the display. The X symbol on the battery indicates that the battery is faulty and is not charging.

Interrupted Treatment / Calendar Indicators

The AccelStim device will disrupt treatment if alarm conditions occur. You will be notified by visual sounds and/or audio messages described in this section. When possible, restore the normal condition and restart treatment by pressing the function button.

Display Message	Audio Signals	Problem and Solution
	Three short beeps every 3 seconds.	**Transducer Not Connected.** Check the connection of the transducer to the AccelStim device and press the function button to start the treatment.
	Three short beeps every 3 seconds.	**Treatment Not Allowed.** The AccelStim device allows a maximum of two treatments per day. Only complete two treatments per day if instructed by your physician. If two treatments have been completed, no other treatments are allowed. The AccelStim device will switch off automatically after 30 seconds. ***The second treatment must be completed by midnight on the current day.***
	Three short beeps every 3 seconds.	**Expired Device Life.** The AccelStim device provides daily treatment for up to 365 days from date of first use. The AccelStim device switches off automatically after 30 seconds. Contact Patient Service at 1-800-535-4492.
	Three short beeps every 3 seconds.	**Fault Detected.** If the AccelStim device detects an anomaly in the transducer or device operation, treatment is stopped. Check the presence of gel on the transducer which must form a 1-2 mm thick layer to the transducer. Then restart the treatment by pressing the function button. If the message remains after checking the gel, turn the device off and contact Patient Services at 1-800-535-4492.
 	Three short beeps every 3 seconds.	**Over Current Fault Detected in Calendar or stand-by mode.** If over current fault detected, the AccelStim device will switch off automatically after 5 seconds. Contact Patient Services. **NOTE:** If detected over current condition when export treatment data to USB portable drive, please try again while device is charging or after the device battery is fully charged.

Display Message	Audio Signals	Problem and Solution
 	No Audio	**Internal Battery Damaged.** Recharging the AccelStim device is not possible but it is still possible to perform the treatment by connecting the device to the external power supply. Please contact Patient Services for device replacement. When performing the treatment with a faulty battery, the AccelStim device will automatically start in treatment mode a few seconds after the power supply is connected and in the upper right corner of the screen the battery symbol with an X will be displayed. At the end of the treatment, it is necessary to disconnect the power supply from the AccelStim device to power down the device. In the case of a faulty battery, it is not possible to turn on the AccelStim device to calendar mode. ***The two visual alerts in this section have the same meaning.**

STORAGE AND OPERATING ENVIRONMENTS

When moving the AccelStim device from very cold or very hot storage areas (like your car), wait at least an hour to use or charge the device. The device requires time to return to a safe operating temperature

Environmental Operating Conditions (Lower / Upper Limits)

Ambient temperature: 10/35°C
Relative humidity: 15%/93% (non-condensing)
Atmospheric pressure: 700/1060hPa

Environmental Conditions for Transport and Storage

The system can be transported and stored at the following environmental conditions without risk of any deterioration. **NOTE:** After removing the device from its protective packaging, the environmental operating conditions are applicable for transport and storage between uses.

	Transport	Storage
Ambient temperature	-20/+60°C	5/30°C
Relative humidity	10%/90% (non-condensing)	15%/93% (non-condensing)
Atmospheric pressure	500/1060hPa	700/1060hPa

The AccelStim device is designed for a storage life of 12 months and one year of usage.

THE ACCELSTIM DEVICE CLASSIFICATIONS

- Product Family Name: Orthofix AccelStim Device.
- Equipment is internally powered or may be used with provided external power supply.
- This device generates a low-intensity pulsed ultrasound with a frequency of 1.5 MHz ± 5%. This ultrasound is an acoustic vibration with frequency above the human auditory level, thus the device is silent.
- Storage life for equipment: 12 months.
- Mode of operation: intermittent operation.
- This device is nonsterile. It does not require sterilization.
- Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or nitrous oxide.
- The power supply is considered double insulated with Class II construction.

GENERAL INFORMATION

IEC/EN 60601-1 classification: Device of Class II - Applied part of type BF
Expected lifetime: 2 years.
Generator plastic case: IP22 degree of protection.
Ultrasound transducer case: IPX7 degree of protection.
Battery Internally powered equipment: Li-Ion rechargeable battery - 3,7VDC - 1100mAh - 4,07Wh.
The AccelStim device is isolated from the supply mains by means of a Class II external power supply.

The first digit (IP2x) expresses the degree of protection against the entry of solid objects. Degree of protection 2 means that the device is protected against the entry of solid objects larger than 12 mm Ø (e.g. a finger).

The second digit (IPx2) expresses the degree of protection against the ingress of liquids. The degree of protection 2 means that the device is protected against dripping water at an angle within ± 15 °.

External power supply used as battery recharger		
Model*	ME10A0503B01	**Orthofix reserves the right to provide different models of power supply, tested and approved for the system according to the standard EN60601-1; use only the power supply provided.*
Brand	SL POWER ELECTRONICS	
Input power	100 - 240 VAC	
Mains voltage	50 – 60 Hz	
Max. input current	0,3 A	
Output voltage	5 VDC	
Max output current	2,0 A	
Short-circuit protection	Internal self-resetting protection - Continuous	
Insulation class	II	

OPERATING SPECIFICATION

Ultrasound frequency:	1.5 MHz ± 5%
Pulse width:	200 µsec ± 10%
Repetition rate:	1 KHz ± 10%
Duty factor:	20%
Effective radiating area (ERA):	3.5 cm^2
Temporal average power:	110 mW ± 10%
Effective intensity ISATA:	30 mW/cm^2 ± 30%
Beam non-uniformity ratio (BNR):	3.8 ± 30%
Beam type:	Collimated

The essential performance of the AccelStim device includes the following:

- Free from the display of incorrect numerical values associated with the therapy to be performed.
- 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 assembly surface temperature.

COMPLIANCE STATEMENTS

Changes or modifications not approved by Orthofix could void the user's authority to operate the equipment. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation.

If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

Information Regarding Electromagnetic Compatibility and Immunity

The AccelStim device has been tested and certified as complying with the regulations on electromagnetic compatibility (EMC) of medical devices and has been found suitable for the "Home Healthcare Environment." The AccelStim device can be used in conjunction with other electrical or electronic devices, if they also conform to current standards, without causing interference or interference. The following general requirements need to be observed:

- The AccelStim device should not be used adjacent to, or stacked with, other equipment. If adjacent or stacked use is necessary, the medical electrical equipment or medical electrical system should be observed to verify normal operation in the configuration in which it will be used.
- The AccelStim device needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this accompanying documents.
- None of the device parts are field serviceable. Any unauthorized modifications to the device or components will void the device warranty and compliance.
- The use of accessories, transducers and cables other than those specified and supplied may result in increased emissions or decreased immunity of the device and result in improper operation.
- Portable and mobile RF communications equipment, including peripherals such as antenna cables and external antennas, should be used no closer than 30 cm (12 inches) to any part of the AccelStim device, including cables. Otherwise, degradation of the performance of this medical device could result.

- The AccelStim device can be sensitive to electrostatic discharges with a value > = 4kV. In the presence of such discharges the treatment in progress could be paused. In this case, the user must press the button below the display to restart the treatment.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions
The AccelStim device is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment-Guidance
RF emissions CISPR 11	Group 1	The AccelStim device 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.
RF emissions CISPR 11	Class B	The AccelStim device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration – Electromagnetic Immunity
The AccelStim device is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD)[1] IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.

1 The AccelStim device can be sensitive to electrostatic discharges with a value > = 4kV. In the presence of such discharges the treatment in progress could be paused. In this case, the user must press the button below the display to restart the treatment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % UT (>95 % dip in UT) for 0,5 cycles 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 s	<5 % UT (>95 % dip in UT) for 0,5 cycles 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the medical electrical equipment or medical electrical system requires continued operation during power mains interruptions, it is recommended that the medical electrical equipment or medical electrical system be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE UT is the AC mains voltage prior to application of the test level			

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the AccelStim device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. $d = 2{,}3\sqrt{P}$ 80 MHz to 800 MHz 800 MHz to 2,5 GHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	

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.
NOTE 3 Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

[a] 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. If the measured field strength in the location in which the AccelStim device is used exceeds the applicable RF compliance level above, the AccelStim device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the AccelStim device.
[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the AccelStim device

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

Rated Maximum Output Power of Transmitter W	**Separation Distance According to Frequency of Transmitter** m		
	150 kHz to 80 MHz $d = 1{,}2\sqrt{P}$	80 MHz to 800 MHz $d = 1{,}2\sqrt{P}$	800 MHz to 2,5 GHz $d = 2{,}3\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) 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.			

CLINICAL STUDIES

The Orthofix AccelStim device has been designed to have technical features/device output, patient populations, intended use and indications for use which are similar to a previously approved product.[21] Therefore, the device is expected to perform similarly with regards to safety and performance. The following clinical data collected in support of the US FDA approval[21] for the prior product is therefore being presented in support of the Orthofix AccelStim. Please note that the clinical studies leveraged to support the safety and effectiveness of the AccelStim device may not necessarily be applicable to patients of all races and ethnicities. Such demographic details were not provided in the referenced clinical studies.

Treatment of Nonunion Fractures

Study Design

Three prospectively designed studies, undertaken in the USA, Germany, and the

Netherlands, were submitted to the FDA[21] as the basis for approval of the EXOGEN Bone Healing System to treat established nonunions. The studies had a self-paired control design with each nonunion case serving as its own control, and with the prior treatment result of failed orthopedic care as the control compared to ultrasound as the only new treatment. The criterion for the definition of nonunion cases was the minimum time from fracture of nine months. The primary efficacy outcome was healed due to EXOGEN treatment, as judged clinically (no pain upon palpation or weightbearing) and radiographically (3 out of 4 cortices bridged).

Clinical Results

Analyzing the data from Germany, the completed cases had a healed rate of 86% (64/74) with a mean time to a healed fracture of 163±9.4 days. The median heal time was 142 days with a range of 53 to 375 days. The mean fracture age for the healed cases was 494 days with a range of 257-6011 days. The scaphoid nonunion heal rate of 33% (2/6) was attributable to the three scaphoid nonunion failures 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 such as those with ORIF (Open Reduction Internal Fixation) and those cases with intramedullary rods had an 88% (21/24) and 100% (16/16) healed rate, respectively. The results of this nonunion paired design clinical study established the safety and efficacy of the EXOGEN Bone Healing System in treating nonunions. This includes cases that had long fracture ages of up to five years but suggests that nonunions with of over five years duration may have a decreased response to ultrasound treatment. The results are summarized in Table 1.

Nolte et al.,[19] reporting on the Netherlands study, confirmed the 86% (25/29) success rate and showed the average heal time to be around five months without additional intervention. Average nonunion fracture age was 61 weeks. There were high success rates seen with atrophic and oligotrophic non-unions (80% and 92% respectively) where some biological deficiency may contribute to the original nonunion. Additionally the application of EXOGEN to hypertrophic nonunions, which might usually be considered as requiring revised treatment to correct fracture instability, was successful in 80% of cases. Success was seen for a range of bones, all types of typical primary fracture management, and across all patient age ranges. For the United States study, the completed cases group had an 82% (352/429) heal rate.

Other Nonunion Studies

Frankel and Mizuno[2] in their analysis of the 1,546 USA patient nonunion registry demonstrated that for patients with risk factors that may impair fracture healing, such as alcoholism, smoking, diabetes, vascular problems, or steroid use, there was no significant change in the effectiveness of the EXOGEN Bone Healing System.High success rates were achieved for all bones, regardless of fracture age, but there was a trend towards higher success rates and faster healing with earlier intervention.

Strauss and Gonya[23] described the effects of low-intensity pulsed ultrasound on two difficult cases of Charcot nonunions with multiple prior failed surgical procedures. Both

cases healed within 5.5 months when treated with the combination of low-intensity pulsed ultrasound and intramedullary fracture nailing.

Acceleration of Conservatively Treated Fresh Distal Radius Fractures

Study Design

Placebo-controlled, randomized, double-blind multi-center study with the prospectively defined primary end-point of a combination of clinical and radiographic healing (4 out of 4 cortices bridged as judged by the blinded principal investigator). Sixty one fractures with conservatively treated cancellous radial fractures were randomized into the EXOGEN treated and control groups (Kristiansen et al.[10]).

Patient Population and Demographics

The demographics of the trial participants were comparable across treatment and control groups with regard to age, sex, fracture characteristics, interval between fracture and change to: treatment of fracture, and duration of follow-up. Race and ethnicity of trial participants were not provided. Results of this study may not necessarily be applicable to patients of all races and ethnicities.

Evaluation Schedule

Treatment was started within seven days of the fracture, and patients instructed to use the device until the 10 week follow-up visit. Duration of immobilization in the cast was determined by the site investigator. Patients were scheduled to return for follow-up at 1, 2, 3, 4, 5, 6, 8, 10, 12 and 16 weeks.

Clinical Results

EXOGEN treatment accelerated healing by 38% (61±3.4 days in the active group versus 98±5.2 days in the control group; $p<0.0001$).

The effect of EXOGEN pulsed low-intensity ultrasound on fracture reduction during healing was also assessed. The subset of fractures which were satisfactorily reduced having presented with at least 10 degrees of negative volar angulation were analyzed. The active group demonstrated significantly smaller loss of reduction compared to the placebo group ($p<0.01$).

Acceleration of Conservatively Treated Fresh Tibial Fractures

Study Design

Placebo-controlled, randomized, double-blind multi-center study with the prospectively defined primary endpoint of a combination of clinical and radiographic healing (3 out of 4 cortices bridged as judged by the blinded principal investigator). Sixty seven patients with conservatively treated closed or Grade I open, cortical diaphyseal tibia fractures were randomized into the EXOGEN® (SAFHS® Model 2A) treated and control groups (Heckman et al.[9]).

Patient Population and Demographics

The demographics of the trial participants were comparable across treatment and control groups with regard to age, sex, fracture characteristics, interval between fracture and treatment of fracture, duration of follow-up, and days to start weight-bearing. Race and ethnicity of trial participants were not provided. Results of this study may not necessarily be applicable to patients of all races and ethnicities.

Evaluation Schedule

Treatment was started within seven days of the fracture, and continued for 20 weeks or until the clinical investigator judged the fracture to have healed. All patients were scheduled for follow-up radiographs at 4, 6, 8, 10, 12, 14, 20, 33 and 52 weeks after the fracture. Clinical follow-up evaluations were performed at the time of any cast change (usually at 6 and 10 weeks) and at the follow-up visit when radiographic evaluation indicated the fracture had healed sufficiently to allow removal of the cast.

Clinical Results

EXOGEN treatment induced a 38% acceleration in achieving the prospectively defined primary endpoint of a combination of clinical and radiographic healing (96±4.9 days in the active group versus 154±13.7 days in the control group; p = 0.0001).

Analysis of Fresh Fracture Studies

Cook et al.[1] retrospectively studied the tibial and distal radius fracture data of Heckman et al. [9] and Kristansen et al. [10] to analyze the impact of low-intensity pulsed ultrasound on the incidence of delayed unions, and on the healing time of smokers. Significant reductions in time to healing of tibial shaft fractures were observed in the active ultrasound treatment group with casting versus the casting only placebo control group (a 41% reduction for those who smoked, $p<0.006$; a 26% reduction for nonsmokers, $p<0.05$). Similarly, the distal radius fractures treated with the ultrasound device also showed decreases in healing time compared to placebo control group (51% faster active healing rate in smokers, $p<0.003$; 34% faster active healing in nonsmokers, $p<0.0001$).

Heckman et al.[9] reported similar results in a group of tibial fractures treated with the ultrasound device as compared to placebo control. There was a statistically significant decrease in the time to clinical healing (86 +/- 5 days vs. 114 +/- 10.4 days, p=0.01) and also a significant decrease in the time to overall clinical and radiographic healing (96 +/- 4.9 days vs. 154 +/- 13.7 days, p=0.0001).

Table 1: Efficacy Results for SAFHS® Treated Completed Cases *

	Categorical Variable Prior to Start of SAFHS® Treatment	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:** <65kg.	12	11	1	92%	0.65
	65-80 kg.	35	31	4	89%	
	>80kg	27	22	5	81%	
4	**Fracture Age:**					0.001
	256-356 days	20	19	1	95%	
	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 and All Subsequent Interventions:**					0.16
	0	20	15	5	75%	
	1	15	12	3	80%	
	2	24	23	1	96%	
	3 or more	15	14	1	93%	
6	**Prior Days without Surgery (Days from Last Surgical Procedure SAFHS® start):**					0.03
	< 82	9	9	0	100%	
	83-365	39	34	5	87%	
	366-730	12	12	0	100%	
	>731	14	9	5	64%	

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

Table 1: Efficacy Results for SAFHS® Treated Completed Cases *

7	**Bone:** Tibia/Tibia-Fibula/Fibula Femur Radius/Radius-Ulna/Ulna Humerus Metatarsal Other Foot Bones (calcaneus) Ankle* Scaphoid Other Hand Bones (metacarpal) Other (4-clavicle, 1-pelvis, 1-rib) *Tibio-talar arthrodesis	28 13 7 6 4 1 2 6 1 6	26 12 6 5 4 1 1 2 1 6	2 1 1 1 0 0 1 4 0 0	93% 92% 86% 83% 100% 100% 50% 33% 100% 100%	0.03
8	**Long Bone vs. Other Bones:** **Long Bones** -28 tibia -13 femur -7 radius -6 humerus -4 metatarsal -1 metacarpal **Other Bones** -1 calcaneus -4 clavicle -1 pelvis -1 rib -6 scaphoid -2 ankle	59 15	54 10	5 5	92% 67%	0.02
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 Bones Cases:** Missing Metaphyseal Diaphyseal	(5) 8 46	(3) 6 45	(2) 2 1	 75% 98%	0.05

Table 1: Efficacy Results for SAFHS® Treated Completed Cases *

11	**Initial Fracture Type:**					
	Missing	(4)	(2)	(2)		
	Closed	40	34	6	85%	0.16
	Open	22	21	1	95%	
	Arthrodesis	2	1	1	50%	
	Osteotomy	6	6	0	100%	
12	**Fixation Present at Start of and During SAFHS® Treatment**					
	IM Rod; Only for Long Bone Cases (N=59)					
	No	43	38	5	88%	
	Yes	16	16	0	100%	0.31
	Open Reduction, Internal Fixation (ORIF)					
	No	51	44	7	86%	
	Yes	24	21	3	88%	1.00
	External Fixation; Only for Long Bone Cases (N=59)					
	No	50	46	4	92%	
	Yes	9	8	1	89%	0.58
	Conservative (Cast, Splint, Brace)					
	No	59	52	7	88%	
	Yes	16	13	3	81%	0.44
	IM Rod, or ORIF, or External Fixation, or Conservative					
	No	11	8	3	73%	
	Yes	64	57	7	89%	0.16
13	**Prior Failed Lithotripsy Therapy:**					
	No	73	63	10	86%	1.00
	Yes	2	2	0	100%	
14	**Smoking Status:**					
	Missing	(2)	(2)	(0)		
	Never Smoked	34	31	3	91%	0.47
	Stopped Smoking Prior to SAFHS® Start	10	8	2	80%	
	Smoke at the SAFHS® Start	28	23	5	82%	
15	**Nonunion Type:**					
	Missing	(22)	(17)	(5)		
	Atrophic	41	36	5	88%	0.57
	Hypertrophic	11	11	0	100%	

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

Conclusions Drawn from the Studies

The information provided provides reasonable assurance of the safety and effectiveness of the AccelStim device for the noninvasive except skull and vertebra treatment of established nonunions, fresh, closed, posteriorly displaced distal radius fractures and fresh, closed, or Grade I open tibial diaphysis fractures. Clinical studies leveraged to support the safety and effectiveness of the AccelStim device may not necessarily be applicable to patients of all races and ethnicities. Such demographic details were not provided in the referenced clinical studies.

REFERENCES

1. Cook SD, Ryaby JP, McCabe J, Frey JJ, Heckman JD, Kristiansen TK. Acceleration of tibia and distal radius fracture healing in patients who smoke. Clin Orthop Relat Res. 1997;337:198-207.
2. Frankel VH, Mizuno K. Management of nonunion with pulsed, low-intensity ultrasound therapy-international results. Surg Technol Int. 2001;X:1-6.
3. Frankel VH. Results of prescription use of pulsed ultrasound therapy in fracture management. Surg Technol Int. 1998; VII:389-393.
4. Fujioka H, Tanaka J, Yoshiya S, Tsunoda M, Fujita K, Matsui N, Makino T, Kurosaka M. Ultrasound treatment of nonunion of the hook of the hamate in sports activities. Knee Surg Sports Traumatol Arthrosc. 2004;12(2):162-164.
5. Fujioka H, Tsunoda M, Noda M, Matsui N, Mizuno K. Treatment of ununited fracture of the hook of hamate by low-intensity pulsed ultrasound: a case report. J Hand Surg. 2000;25(1):77-79.
6. Furue Y. The effect of low-intensity pulsed ultrasound for treatment of nonunion. Orthopaedic Surgery and Traumatology (Japanese language). 2000;43(3):231-235.
7. Hadjiargyrou M, McLeod K, Ryaby JP, Rubin C. Enhancement of fracture healing by low intensity ultrasound. Clin Orthop Relat Res. 1998;(355S):S216-229.
8. Handolin L, Kiljunen V, Arnala I, Pajarinen J, Partio EK, Rokkanen P. The effect of low intensity ultrasound and bioabsorbable self-reinforced poly L-lactide screw fixation on bone in lateral malleolar fractures. Arch Orthop Trauma Surg. 2005;125(5):317-21.
9. Heckman JD, Ryaby JP, McCabe J, Frey JJ, Kilcoyne RF. Acceleration of tibial fracture-healing by non-invasive, low-intensity pulsed ultrasound. J Bone Joint Surg. 1994;76-A(1):26-34.
10. Kristiansen TK, Ryaby JP, McCabe J, Frey JJ, Roe LR. Accelerated healing of distal radial fractures with the use of specific, low-intensity ultrasound. J Bone Joint Surg. 1997;79-A(7):961-973.
11. Lerner A, Stein H, Soudry M. Compound high-energy limb fractures with delayed union: our experience with adjuvant ultrasound stimulation (Exogen). Ultrasonics. 2004;42(1-9):915-917.
12. Mayr E, Frankel V, Rüter A. Ultrasound-an alternative healing method for nonunions? Arch Orthop Trauma Surg. 2000;120:1-8.
13. Mayr E, Laule A, Suger G, Rüter A, Claes L. Radiographic results of callus distraction aided by pulsed lowintensity ultrasound. J Orthop Trauma. 2001;15(6):407-414.
14. Mayr E, Möckl C, Lenich A, Ecker M, Rüter A. Is low intensity ultrasound effective in treating disorders of fracture healing? Unfallchirurg. 2002;105:108-115.
15. Mayr E, Rudzki MM, Borchardt B, Haüsser H, Rüter A. Does pulsed low intensity ultrasound accelerate healing of scaphoid fractures? Handchir Mikrochir Plast Chir. 2000;32:115-122.
16. Mayr E, Wagner S, Ecker M, Rüter A. Ultrasound therapy for nonunions (pseudarthrosis): three case reports. Unfallchirug. 1999;102(3):191-196.
17. Narasaki K. Low intensity ultrasound treatment of nonunion and delayed union cases. Orthopaedic Surgery and Traumatology (Japanese language). 2000;43(3):225-230.
18. Nolte PA, Klein-Nuland J, Albers GHR, Marti RK, Semeins CM, Goei SW, Burger EH. Low-intensity ultrasound stimulates in vitro endochondral ossification. J Orthop Res. 2001;16(2):16-22.
19. Nolte PA, van der Krans A, Patka P, Janssen IMC, Ryaby JP, Albers GHR. Low-intensity pulsed ultrasound in the treatment of nonunions. J Trauma. 2001;51(4):693-703.
20. Pilla AA, Figueiredo M, Nasser PR, Alves JM, Ryaby JT, Klein M, Kaufmann JJ, Siffert RS. Acceleration of bone-repair by pulsed sine wave ultrasound: animal. Clinical and mechanistic studies. In Electromagnetics in Biology and Medicine, ed. by CT Brighton and SR Pollock, San Francisco Press. 331-341, 1991.
21. Premarket Approval P900009/Supplement 6, Summary of safety and effectiveness data: low-intensity pulsed ultrasound device for the noninvasive treatment of nonunions.
22. Sato W, Matsushita T, Nakamura K. Acceleration of increase in bone mineral content by low-intensity ultrasound energy in leg lengthening. J Ultrasound Med. 1999;18:699-702.
23. Strauss E, Gonya G. Adjunct low intensity ultrasound in charcot neuroarthropathy. Clin Orthop Relat Res. 1998;349:132-138.
24. Warden SJ, Bennell KL, McMeeken JM, Wark JD. Acceleration of fresh fracture repair using the sonic accelerated fracture healing system (EXOGEN): a review. Calcif Tissue Int. 2000;66:157-163.
25. Yoshitaka H, Toshiharu S, Osamu U, Toshifumi K, Kazuhisa B. Effect of low internisty ultrasound on severe open fractures. Seikei Geka (Orthopaedic Surgery and Traumatology) (Japanese language). 2003;46(1):67-73.
26. Ziskin MC. Report on the safety of the Therasonics Medical Systems EXOGEN unit, model 2A. PMA900009, vol. 3, section VI.A.1, 209-234.

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See page 18 of this manual for details.

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