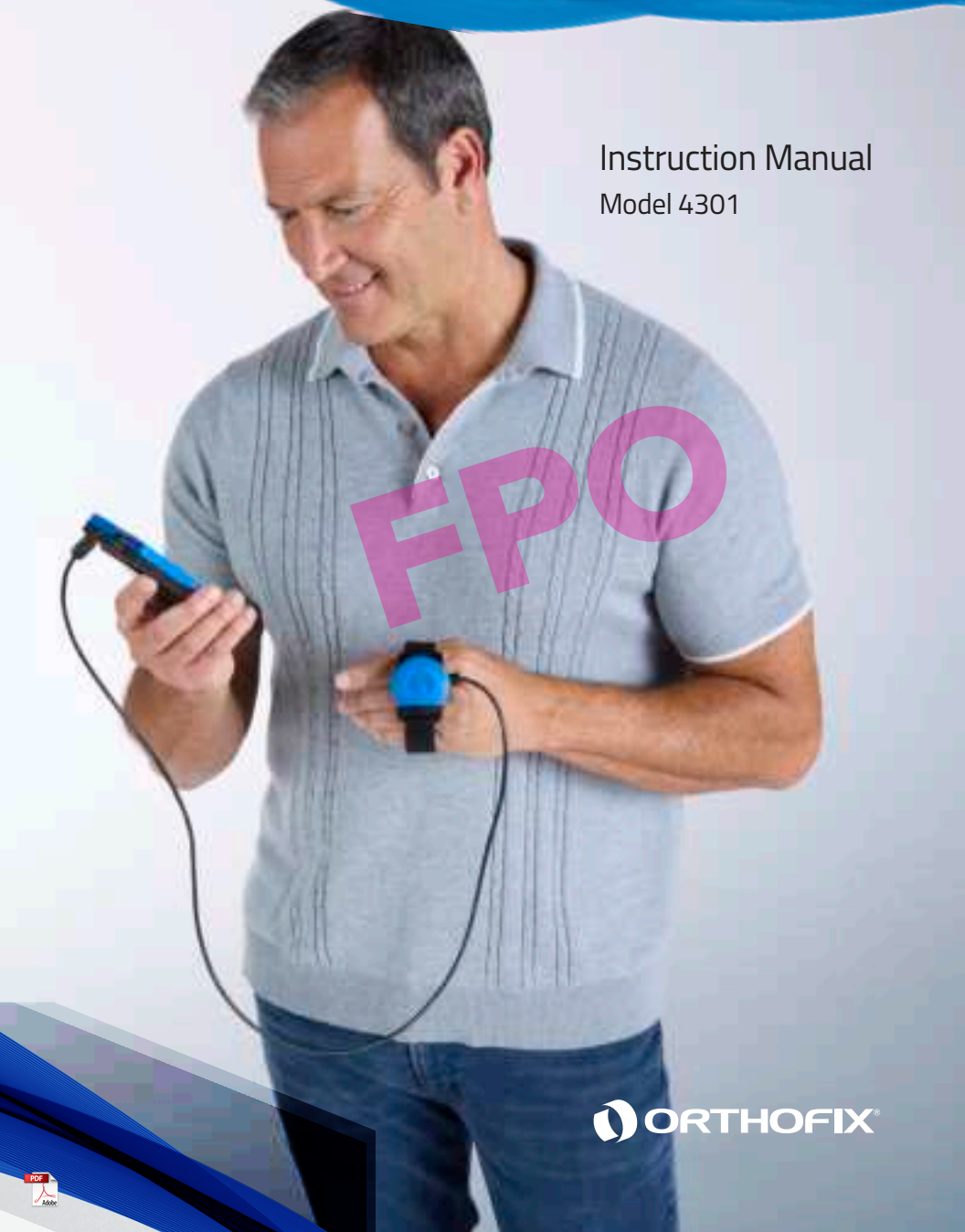
AccelStim™

Bone Healing Therapy

Instruction Manual

Model 4301



ORTHOFIX®

Symbol		Meaning
	IEC 60417-5009	**Stand-by Button:** Used to turn the unit on and off
		**Play Button:**
	ISO 15223-1 5.1.6	**Catalogue number:** This symbol specifies the catalogue number so that the medical device can be identified.
	ISO 15223-1 5.1.7	**Serial number:** This symbol specifies the medical device serial number.
	IEC 60601-1 ISO 7010-M002	**Refer to Instruction Manual/Booklet:** 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 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.
	21 CFR 801.109	**Prescription only**
	ASTM F2503-05	**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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Device Box Components

1 - AccelStim Device with Ultrasound Transducer
1 - Literature Pack
1 - Elastic Strap with Transducer Holder
1 - Power Supply
1 - Ultrasound Gel

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.

Device Components

Model 4301

Figure 1: AccelStim device components

AccelStim device (see figure 1)

The AccelStim device is equipped with:

- A touch screen display and audible indicators which provide important feedback during treatment.

  1. Battery charge status
  2. Daily treatment timer
  3. Treatment execution symbols and error messages

- One button

  4. Stand-by button, marked with ⏻ symbol. This button is used to power the unit on and off.

Ultrasound Transducer

Place the transducer in the transducer holder with the writing facing upward. The holder is connected to the strap, as shown in Figure 2. Position the transducer holder directly over the treatment area.

Figure 2 : 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)

An external power supply to charge the battery is provided with the device. Use only the Orthofix provided power supply to charge the battery. The use of an alternative charger can cause permanent damage to your device and render it unusable.

Figure 3: Power Supply (Charger)

Device Life and Usage

The AccelStim device should be worn for 20 minutes each day, as prescribed by your physician. It's recommended to use the device at the same time daily. Your physician will determine the overall length of treatment based on your individual fracture healing progress. This may span several weeks or months. The AccelStim device is capable of providing 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.

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.

Additional Warnings include:

- 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.

- The use of accessories, detachable parts, and materials other than those specified and supplied may result in increased emissions or decreased immunity of the device and result in improper operation.
- Do not connect the AccelStim device to any component not intended for use and not supplied by the manufacturer.
- Do not connect any part of the unit to other equipment or devices.
- Position the AccelStim device in charging position so that it is easily unplugged from the outlet.
- Strangulation Hazard - Keep the AccelStim device and its accessories away from small children and pets. This device is not a toy and may be hazardous to children and pets.
  For example:
  - A choking hazard may exist for detachable parts
- Modification of equipment can be unsafe. Please contact the manufacturer if modifications are needed.

Precautions

- The AccelStim device will not correct or change the position of your fracture after it has been initially set and placed in a cast. It cannot fix issues such as displacement, angulation, or misalignment of the bone.
- 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.
- 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 cm^2 (3.5 square centimeters) of the transducer is likely to benefit from the AccelStim device's treatment. Therefore, the physician and patient should take care in appropriately placing 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.
- Where the device has contact with the skin, patients and caretakers should assess for adverse reactions such as redness (erythema), swelling (edema), irritation, sensitization (delayed Type IV hypersensitivity), allergy, immune response, or other reactions. Stop use if any reactions are detected.

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/cm^2 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/cm^2), 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 Accessories

An accessory available to the patient is a user-friendly mobile application, STIM onTrack. STIM onTrack easily allows the patient to monitor their device use. More information about this mobile application and its use can be found on our patient education website: www.BoneGrowthTherapy.com

In addition, the AccelStim device features straps that can be removed and replaced if they become worn or damaged through regular use.

A casting kit and weighted strap are also available for the AccelStim device. If needed, please refer to your physician, sales representative, or patient education website for more information.

If replacement accessories are needed, please contact Patient Services at 1-800-535-4492.

DEVICE OPERATION

The AccelStim device can only be powered with an internal battery when delivering treatment.

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 holder, and strap will be needed to treat your fracture. If the fracture is stabilized via a cast, please refer to the cast guide. 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 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. 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. 2. Open the blue cover of the transducer holder by rotating it counterclockwise.
	3. 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.
	4. Insert the transducer inside the transducer holder so that the serial number is visible. 5. Close the blue cover by rotating it clockwise.

STARTING A TREATMENT

Battery Status Indicator
The battery status is characterized by several notches to indicate the level of charge for the device.

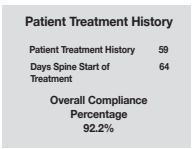
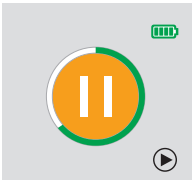
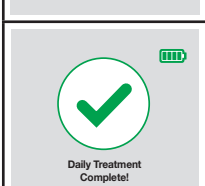
Treatment Time Indicator
The prescribed treatment time to complete a treatment session for the day.

Visible in minute and second increments.

Play Button
Pressing the play symbol will start the treatment and signal the AccelStim device with a beep. See details in the Performing a Treatment section..

Device Stand-by Button
Press the Stand-by button to turn the device on and off.

Performing a Treatment

	1. Turn the device on by pressing the Stand-by button and release it when you hear the beep. Then the display screen will light up. 2. The Orthofix logo will appear on the display screen as the device powers on.
	3. The Patient Treatment History screen is displayed with the overall compliance percentage for your prescribed treatment.
	4. Prior to treatment, the device will flash the text "GEL" until the user has applied the ultrasound gel to the transducer (applied to the side with no writing). 5. Click the arrow button on the bottom right side of the screen to acknowledge gel has been applied and continue to the treatment screen. **NOTE:** If more than one treatment is completed in a day, the treatment complete screen may show before the Gel screen.
	6. The device will display a 20 - minute treatment time along with a play symbol to specify device is now ready for treatment. 7. To start treatment, press the play button on the bottom right side of the screen. The AccelStim device signals the start of treatment with a beep.
	8. During treatment, the device screen displays the remaining therapy time and a pause button.
	9. To pause the device in the middle of a treatment, press the pause button on the bottom right side of the screen and the treatment will stop. The screen will display a pause symbol. 10. To resume treatment, press the play button on the bottom right side of the screen. The countdown will resume at the remaining daily treatment time.
	11. Once the treatment time reaches zero, the device screen displays a check mark to specify treatment is completed and emits three medium beeps. **NOTE:** After five seconds, the device will display an updated compliance summary screen (as seen in step 3) for 15 seconds before automatically shutting down.

NOTE: The AccelStim device will automatically timeout after five minutes in the following screens: GEL, Treatment, and Pause.

NOTE: If timed out, turn the device on to restart/continue a treatment.

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. Once treatment is completed, open the blue cover of the transducer holder by rotating it counterclockwise. 2. Gently remove the transducer from the transducer holder.
	3. Gently clean the transducer with a slightly damp cloth using water or a neutral detergent, such as household liquid dishwashing detergent.
	4. 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.

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 the battery status indicator on the upper right corner of the screen. When the battery level decreases to a low battery level, the battery icon will change to red, emit short beeps, and blink the battery icon three times every five minutes to remind the user that the battery needs to be recharged after treatment is completed.

If the device is not recharged and the battery level has reached an exceptional low level, the device will emit four medium beeps, display an "E" prefixed eight digit number and power down after 12 seconds. Please recharge the device battery before continuing your daily treatment.

Recharging the AccelStim device Battery

To recharge the battery within the AccelStim device, follow these steps:

	1. Connect the power supply to the device. 2. Plug the charger in the wall outlet.
	3. When the power supply is connected to the device, the screen will display a blinking lightning icon to indicate the charging process has started.
	4. When the charging process is completed the full battery symbol is displayed with a checkmark.

NOTE: The device will not deliver treatment while charging.
WARNING: If the device doesn't power on or start charging when connected to the power supply, try plugging the power supply directly into an AC wall outlet. If this doesn't resolve the issue, contact Patient Services at 1-800-535-4492 for assistance.

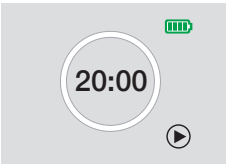
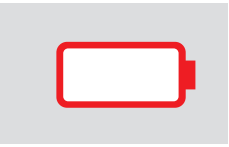
Device Use and Device Care

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 events 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/Interrupted Indicators section.
- 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.
- 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. Be sure to remove the source of disturbance before continuing the treatment if closer than 30 cm (12 inches).

VISUAL AND AUDIO BATTERY INDICATORS

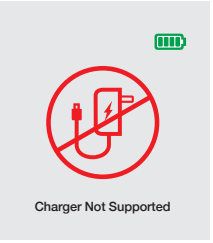
The AccelStim device will disrupt operation if alarm conditions occur. You will be notified by visual sounds and/or audio messages described in this section. If further technical assistance is required, please contact Patient Services at 1-800-535-4492.

	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 red low battery icon will display to indicate the need to connect the power supply to recharge the device battery. When the battery is low the device will emit three short beeps and the low battery icon will blink three times until the device is connected to the power supply.
	When the power supply is connected to the device, the screen will display a blinking lightning icon to indicate the charging process started. WARNING: In case of a faulty power supply, the blinking lightning icon does not appear. Contact Patient Services at 1-800-535-4492 for assistance.
	When the charging process is completed the full battery symbol is displayed with a checkmark.
	If a faulty battery is detected when the device is turned on and the charging process is not possible, a battery symbol with a line through it will appear on the screen. Contact Patient Services at 1-800-535-4492 for assistance.

NOTE: Position the device so that it is easily unplugged from the outlet.

Troubleshooting / Interrupted 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
	Two Long Beeps	**Expired Device Life:** The device provides daily treatment for up to 365 days from the date of first use. The device emits two long beeps and displays the E315 code for five minutes or until being turned off.
	Two Long Beeps	**Fault Detected:** If the device detects an anomaly the screen will display a warning red 'X,' and treatment is stopped. Check the presence of gel on the transducer and restart the treatment by pressing the Stand-by button. If this message remains after checking the gel, turn the device off and contact Patient Services at 1-800-535-4492.
		Only use the Orthofix-supplied Power Charger. The use of an Alternative Charger can cause permanent damage to your device and render it unusable.

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

When new, a fully charged battery can provide up to five treatments before requiring a recharge. However, over time, this number may gradually decrease. Towards the end of its life, the battery may only be able to deliver one treatment. It is best practice to recharge the AccelStim device after each use.

THE ACCELSTIM DEVICE CLASSIFICATIONS

Product Family Name: Orthofix AccelStim Device.

- The power supply is only used to charge the battery; the device cannot provide treatment with the power supply attached.
- 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.

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.

GENERAL INFORMATION

IEC/EN 60601-1 classification: Device of Class II - Applied part of type BF
Expected lifetime: 1 year on the shelf + 1 year of expected service life.
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*	WR9QA1500USBCNAIMR6B	**Orthofix reserves the right to provide different models of power supply, tested and approved for the system according to the standard IEC60601-1 or IEC62368-2; use only the power supply provided.*
Brand	GLOBTEK, INC	
Input Voltage	100 - 240 VAC	
Input frequency	50 – 60 Hz	
Max. input current	0.6 A	
Output voltage	5 VDC	
Max output current	1.5 A	
Short-circuit protection	Auto-restart	
Insulation class	II	

OPERATING SPECIFICATION

Acoustic working frequency:	1.5 MHz ± 5%
Waveform:	Pulsed
Pulse duration:	200 µsec ± 10%
Pulse repetition period:	1 ms +/- 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

CYBERSECURITY INFORMATION ABOUT THIS MEDICAL DEVICE

To ensure the safety and security of the AccelStim device and your personal information, following the provided guidelines and security measures is recommended. Keep the device and any associated data protected at all times by reviewing the following information in this section.

- The device stores a calendar with the number of minutes it was used each day.
- The device keeps a log, or history, of actions performed on it to help diagnose any reported problems.
- Your device does not store any personal information.
- Your device automatically communicates to the STIM onTrack application when the app is loaded and open on a Bluetooth enabled phone.
- The device stores your local time zone. You can change this in the device's settings menu. The time zone will automatically be updated when the device is on and the STIM onTrack app is open.
- The device will also update usage data and display status when the device is on and the STIM onTrack app is open
- Always safeguard your medical device and keep it in your possession.
- Only use the Orthofix-supplied power charger. The use of an alternative charger can cause permanent damage to your device and render it unusable.
- Regularly inspect the device and accessories for signs of tampering, such as removed screws or labels.
- After your treatment is completed and your physician has advised you to discontinue use, please contact Patient Services for further information on our free recycling program.
- A copy of the device software bill of materials (SBOM) may be requested by calling Patient Services.

In the event of a cybersecurity incident affecting the AccelStim device, Orthofix will promptly notify individuals with contact information on file. If your information has changed, please update it by calling Patient Services at 1-800-535-4492. More information on cybersecurity recommendations can be found in the STIM onTrack instructional guide.

Your AccelStim device is designed with your safety in mind. It includes several important features to ensure proper therapy:

Accurate Display: The device shows correct information about your therapy on its screen.

Controlled Ultrasound: It produces only the intended ultrasound output for your treatment.

Safe Output Levels: The ultrasound output is kept within safe limits.

Temperature Control: The part of the device that touches your skin (the transducer) is designed to maintain a comfortable temperature.

These features work together to provide you with safe and effective treatment.

COMPLIANCE STATEMENTS

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference and (2) this device must accept any interference received, including interference that may cause undesired operation.

Changes or modifications not approved by Orthofix could void the user's authority to operate the equipment. This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. 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.

This device contains license-exempt transmitter(s)/ receiver(s) that comply with Innovation, Science and Economic Development Canada's license-exempt RSS(s). Operation is subject to the following two conditions: 1. This device may not cause interference; 2. This device must accept any interference, including interference that may cause undesired operation of the device.

L'émetteur/récepteur exempt de licence contenu dans le présent appareil est conforme aux CNR d'Innovation, Sciences et Développement économique Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes: 1. L'appareil ne doit pas produire de brouillage; 2. L'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

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. The following general requirements must 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 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, detachable parts, and materials 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.

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.
N/A	N/A	
N/A	N/A	

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	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 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 100 kHz repetition frequency	± 2 kV 100 kHz repetition frequency	Mains power quality should be that of a typical commercial or hospital environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Surge IEC 61000-4-5	± 0.5 kV, ± 1 kV Line to Line ± 0.5 kV, ± 1 kV, ± 2 kV Line to Ground	± 0.5 kV, ± 1 kV Line to Line ± 0.5 kV, ± 1 kV, ± 2 kV Line to Ground	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	0% UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° 0% UT; 1 cycle and 70% UT; 30 cycles Single phase: at 0° 0% UT; 300 cycles	0% UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° 0% UT; 1 cycle and 70% UT; 30 cycles Single phase: at 0° 0% UT; 300 cycles	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.
Immunity to proximity fields from RF wireless communications equipment IEC 60601-1-2 Clause 8.10	27 V/m 385 MHz 28 V/m 450 MHz 9 V/m 710 MHz 9 V/m 745 MHz 9 V/m 780 MHz 28 V/m 810 MHz 28 V/m 870 MHz 28 V/m 930 MHz 28 V/m 1720 MHz 28 V/m 1845 MHz 28 V/m 1970 MHz 28 V/m 2450 MHz 9 V/m 5240 MHz 9 V/m 5500 MHz 9 V/m 5785 MHz	27 V/m 385 MHz 28 V/m 450 MHz 9 V/m 710 MHz 9 V/m 745 MHz 9 V/m 780 MHz 28 V/m 810 MHz 28 V/m 870 MHz 28 V/m 930 MHz 28 V/m 1720 MHz 28 V/m 1845 MHz 28 V/m 1970 MHz 28 V/m 2450 MHz 9 V/m 5240 MHz 9 V/m 5500 MHz 9 V/m 5785 MHz	The frequencies listed represent RF communications equipment in use at the time of publication of the collateral standard.
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 Radiated RF IEC 61000-4-3	3 V 0.15 MHz to 80 MHz 6 V in ISM and amateur radio bands between 0.15 MHz and 80 MHz 80% AM at 1kHz 10 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	3 V 0.15 MHz to 80 MHz 6 V in ISM and amateur radio bands between 0.15 MHz and 80 MHz 80% AM at 1kHz 10 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	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

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 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. This study's results may not necessarily apply 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. This study's results may not necessarily apply 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:**					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	59	54	5	92%	
	-28 tibia					
	-13 femur					
	-7 radius					
	-6 humerus					
	-4 metatarsal					
	-1 metacarpal					
	Other Bones	15	10	5	67%	
	-1 calcaneus					
	-4 clavicle					
	-1 pelvis					
	-1 rib					
	-6 scaphoid					
	-2 ankle					
9	**Displaced at the Start of SAFHS® Therapy:**					1.00
	Missing	(5)	(2)	(3)		
	No	56	50	6	89%	
	Yes	13	12	1	92%	
10	**Long Bone Type: Only for Long Bones Cases:**					0.05
	Missing	(5)	(3)	(2)		
	Metaphyseal	8	6	2	75%	
	Diaphyseal	46	45	1	98%	

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					
	No	43	38	5	88%	
	Cases (N=59)					
	Yes	16	16	0	100%	0.31
	Open Reduction,					
	No	51	44	7	86%	
	Internal Fixation (ORIF)					
	Yes	24	21	3	88%	1.00
	External Fixation; Only for					
	No	50	46	4	92%	
	Long Bone Cases (N=59)					
	Yes	9	8	1	89%	0.58
	Conservative					
	No	59	52	7	88%	
	(Cast, Splint, Brace)					
	Yes	16	13	3	81%	0.44
	IM Rod, or ORIF, or External					
	No	11	8	3	73%	
	Fixation, or Conservative					
	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®	10	8	2	80%	
	Start 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%	

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.

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