Accel Heal

ELECTRICAL STIMULATION WOUND THERAPY

Instructions for Use

Accel-Heal® is a Class IIa registered medical device designed to relieve pain and accelerate healing in complex wounds using a proprietary electrical stimulation program.

The treatment uses 6 single use devices. Each Accel-Heal device should be used for 48 hours to deliver 12 days of treatment and may be used during sleep.

Each Accel-Heal treatment pack includes:

6 Accel-Heal devices
12 electrode pads
6 alcohol wipes
Instructions for use

General Advice

⚠ The Accel-Heal treatment has been designed to be applied by either the clinician or the patient, following a consultation.

② Each Accel-Heal device is designed to be a 'single-use' device and must not be reused. Each device should only be used on an individual patient for 48 hours and then discarded. It is not designed or intended to be reprocessed or reused, even on the same patient, and attempting to reuse the device may lead to potentially serious consequences for the patient such as cross infection and contamination.

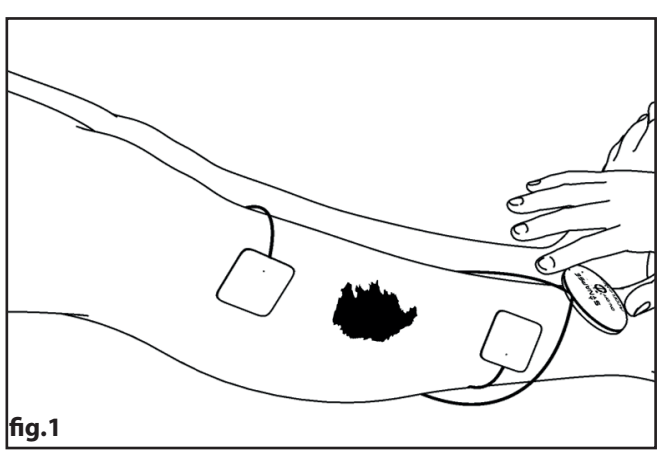

fig.1

Changing the Accel-Heal device

One Accel-Heal device should be applied after each 48 hour interval, following the directions opposite, until the full course of treatment is completed.

The Accel-Heal devices can be disconnected by detaching the Accel-Heal cable connectors from the electrode pad cable receptors.

Applying the treatment

1. Clean the skin surrounding the wound with the alcohol wipes included in the pack.

Attach two electrode pads to the patients skin, either side of the wound or dressing area. Figure 1.

Attach the Accel-Heal device cables to the electrode pad leads by pushing the Accel-Heal cable connectors into the electrode pad cable receptors.

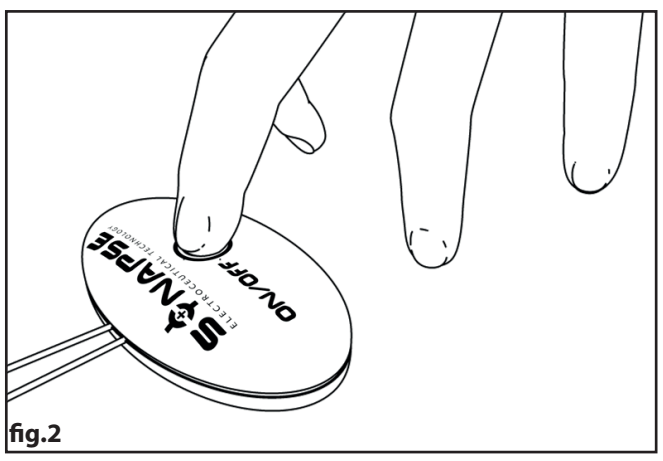

fig.2

Activating the treatment

2. Press and hold the button for two seconds to activate the Accel-Heal device. Figure 2.
When the button is released the device will commence operation and the green LED will flash once every two seconds. Figure 3.

3. The device will run its 48 hour sequence, after which time the device will turn itself off and should be replaced - see 'Changing the Accel-Heal device' opposite.

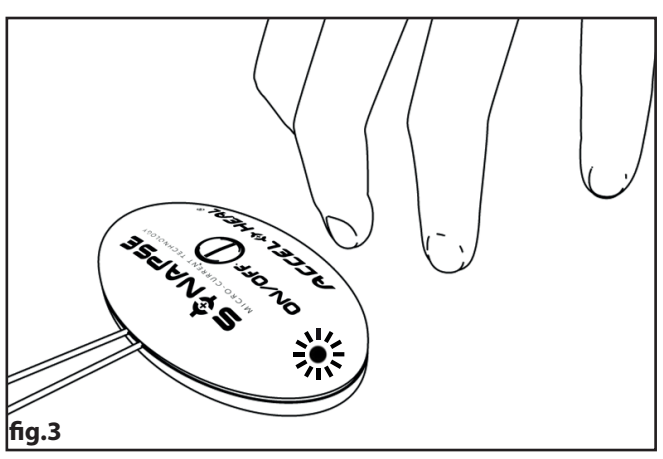

fig.3

Changing the electrode pads

The electrode pads can be changed during the course of treatment, if required.

The treatment provides enough electrode pads and alcohol wipes to clean the skin and change the electrode pads up to 6 times.

Electrode Pads

Only electrode pads that comply with the Medical Device Directive/Regulations should be used with Accel-Heal. No unauthorised extension leads, cables or attachments should be used.

WARNING: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation, such as the device turning off. However, it is unlikely that an adverse event will occur.

Pausing the treatment

To pause the Accel-Heal device mid-use for any reason, press and hold the button for 2 seconds. To restart the device follow the instructions opposite. Figure 2. Please ensure the device is not paused for an extended period of time as this will delay the timing of the next device change.

Trouble Shooting

Problem: The green LED is flashing more quickly, at a rate of twice per second, instead of once every two seconds.

Remedy: There is poor contact between the electrode pads and the skin. Clean the skin and reapply or use new pads.

Problem: The green LED is flashing slowly, at a rate of once every 5-6 seconds.

Remedy: The device program is in a normal period of rest and is operating correctly.

Problem: The green LED is not flashing.

Remedy: The device has completed its treatment course and can be disconnected.

Disposing of used Accel-Heal Devices

Accel-Heal devices are medical electrical devices and should not be disposed of with general waste. Used Accel-Heal devices should be decontaminated and disposed of in a Waste Electrical and Electronic Equipment (WEEE) disposal facility, provided by health establishments.

Returning used Accel-Heal Devices

Used Accel-Heal devices may be returned to Accel-Heal Technologies Limited for WEEE disposal and will only be accepted if accompanied by evidence of decontamination. Contact Accel-Heal Technologies Limited on the telephone number overleaf to arrange a return.

Decontaminating used Accel-Heal Devices

Accel-Heal devices should be decontaminated by wiping them with 70% isopropyl alcohol.

Reprocessing the device or exposing the device to chemicals may lead to a failure of the device.

Treatment Discomfort

Accel-Heal should be pain free and sub-sensory (without feeling). However a tingling sensation may be felt by some users, if not well hydrated, and is normal. If pain or discomfort is experienced stop using Accel-Heal immediately and contact your clinician.

Skin irritation

Ensure skin is clean and dry before electrode pads are applied. If skin irritation develops under or around the electrode pads stop using Accel-Heal and contact your clinician.

Contraindications of Accel-Heal

Heart Conditions

Patients with heart conditions or implanted pacemakers should consult their GP or clinician before using Accel-Heal.

Pregnancy

As a precaution, patients who are pregnant are advised to consult their GP or clinician before using Accel-Heal.

Serious Diseases

Patients with serious diseases, such as cancer, are advised to consult their GP or clinician before using Accel-Heal.

Epilepsy

Patients with epilepsy should consult their GP or clinician before using Accel-Heal and are advised to refrain from using the device near the head.

Varicose Veins and main arteries

Do not place the electrode pads directly over broken capillaries, varicose veins or main arteries.

Warnings

Water

Accel-Heal is an electrical device and should not be used when bathing or if the device becomes wet.

Children

Accel-Heal devices and accessories should be kept out of the reach of children.

Interference

When the Accel-Heal treatment is in use, the devices may interfere with ECG and EEG monitors and alarms. There may also be interference from other electronic devices that affect the performance of the Accel-Heal device. If there are problems increase the separation distance between the devices.

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 0.3m to any part of the Accel-Heal device, including cables specified by the manufacturer. Otherwise, degradation of the performance of the device could result, such as the device turning off. However, the degradation will not cause an adverse event.

WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation, such as the device turning off. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Environmental Conditions for Transport, Storage and Operation

Please ensure Accel-Heal is stored, transported and operated within the temperature range of 0°C-40°C and less than 95% humidity.

Please ensure Accel-Heal is stored and transported between 50 - 106 kPa (atmospheric pressure).

Please ensure Accel-Heal is operated between 70 - 106 kPa (atmospheric pressure).

Guidance and Manufacturer's Declaration
Electromagnetic Emissions
IEC 60601-1-2 for Accel-Heal®

Accel-Heal is suitable for use in the specified electromagnetic environments described below. To prevent the risk of adverse events, customers and/or users should ensure it is used in accordance with the following tables to avoid electromagnetic disturbances.

Emission Test	Professional healthcare Facility Environment	Home Healthcare Environment	Electromagnetic Environment Guidance
Conducted and radiated RF Emissions: CISPR 11	Group 1 Class B	Group 1 Class B	The device does not use RF for its function. Therefore its RF emission are very low and are not likely to cause any interference in nearby electronic equipment. The device is suitable for use in professional healthcare facility environments and home healthcare environments. Exclusions: Professional Healthcare Facility: device is not intended for use in areas of the hospital where there is sensitive equipment or sources of intense electromagnetic disturbances, such as the RF shielded room of an ME system for magnetic resonance imaging, in operating rooms near active HF Surgical equipment, electrophysiology laboratories, shielded rooms, or areas where short wave therapy equipment is used. Home Healthcare Environment: device is not intended for use in helicopters, spacecraft, or submarines. Special Environments: device is not intended for use in Military or heavy industrial areas.
Harmonic distortion IEC	Not applicable	Not applicable	
Voltage fluctuations and flicker	Not applicable	Not applicable	

Guidance and Manufacturer's Declaration
Electromagnetic Immunity
IEC 60601-1-2 for Accel-Heal®

Accel-Heal is intended for use in the electromagnetic environment specified below. The customer and / or the user of the device should assure that it is used in such an environment.

Immunity Test	Immunity Test Levels: Enclosure Port		Compliance Level: Enclosure Port		
	Professional healthcare Facility Environment	Home Healthcare Environment	Professional healthcare Facility Environment	Home Healthcare Environment	Electromagnetic Environment Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	±8 kV contact ± 2kV, ±4 kV, ±8 kV, ±15 kV air		±8 kV contact ± 2kV, ±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%.
Radiated RF EM fields IEC61000-4-3	3 V/m 80 MHz - 2.7 GHz 80% AM at 1 kHz	10 V/m 80 MHz - 2.7 GHz 80% AM at 1 kHz	3 V/m 80 MHz - 2.7 GHz 80% AM at 1 kHz	10 V/m 80 MHz - 2.7 GHz 80% AM at 1 kHz	Portable and mobile RF communications equipment should be used no closer than 0.3m to any part of the device, including cables.
Proximity fields from RF wireless communications equipment IEC 61000-1-3					
Radiated power frequent magnetic fields IEC 61000-4-8	30 A/m 50 Hz or 60 Hz			30 A/m 50 Hz or 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a professional healthcare facility or home healthcare environment.
If electromagnetic disturbances are observed, such as the device turning off, additional separation distance or screening may be necessary.					

Guidance and Manufacturer's Declaration
Electromagnetic Immunity for Accel-Heal®

Immunity Test	Immunity Test Levels: Patient Coupling Port		Compliance Level: Patient Coupling Port		
	Professional healthcare Facility Environment	Home Healthcare Environment	Professional healthcare Facility Environment	Home Healthcare Environment	Electromagnetic Environment Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	±8 kV contact ± 2kV, ±4 kV, ±8 kV, ±15 kV air		±8 kV contact ± 2kV, ±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%.
Conducted disturbances induced by RF fields IEC61000-4-6	3 V 0.15 MHz - 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz	3 V 0.15 MHz - 80 MHz 6 V in ISM and amateur radio bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz	3 V 0.15 MHz - 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz	3 V 0.15 MHz - 80 MHz 6 V in ISM and amateur radio bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz	Portable and mobile RF communications equipment should be used no closer than 0.3m to any part of the device, including cables. The recommended separation distance calculated from the equation application to the frequency of the transmitter. Recommended separation distance: $E = \frac{6}{d}\sqrt{P}$ Where P is the maximum power in W, d is the minimum separation distance in m, and E is the immunity test level in V/m.
If abnormal performance is observed, such as the device turning off, additional separation distance or screening may be necessary.					

Test Specifications for Accel-Heal immunity to RF wireless communications equipment			
Test Frequency (MHz)	Band (MHz)	Modulation	Immunity Test Level (V/m)
385	380-390	Pulse modulation 18 Hz	27
450	430-470	FM ±5 kHz deviation 1 kHz sine	28
710	704-787	Pulse modulation 217 Hz	9
745			
780			
810	800-960	Pulse modulation 18 Hz	28
870			
930			
1720	1700 - 1990	Pulse modulation 217 Hz	28
1845			
1970			
2450	2400 - 2570	Pulse modulation 217 Hz	28
5240	5100 - 5800	Pulse modulation 217 Hz	9
5500			
5785			
If abnormal performance is observed, such as the device turning off, additional separation distance or screening may be necessary. For transmitters rated at a maximum output power not listed above, the recommended separation distance in metres (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.			

Recommended Separation Distances
Between portable and mobile RF communications equipment and Accel-Heal®.

The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum 0.3m distance between portable and mobile RF communications equipment (transmitters) and the device.

Essential Performance
When used in accordance with these instructions for use there are no aspects of device performance that are considered Essential Performance.

Glossary of Symbols Used

Symbol Used	Meaning
	Caution
	Keep Dry
	Keep Out of Direct Sunlight
	Temperature Limitation
	Single Use Only - Do **NOT** Reuse
	WEEE Directive 2002/96/EC Compliant
	Atmospheric Pressure Limitation
	Humidity Limitation
	Accel-Heal is a Type BF Applied Part

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