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.

General Advice

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

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.

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.

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.

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.

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.

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.

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.

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.

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 assume that it is used in such an environment.

Immunity Test

<table>
<thead>
<tr>
<th>Immunity Test</th>
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<th>Compliance Level: Patient Coupling Port</th>
<th>Compliance Level: Enclosure Port</th>
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</thead>
<tbody>
<tr>
<td>Electronic</td>
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<td>±15 kV air</td>
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<tr>
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<tr>
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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.

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, the 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 Immunity for Accel-Heal®

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Glossary of Symbols Used