URGENT MEDICAL DEVICE RECALL

HeartSine Technologies Pad-Pak/Pedi-Pak

TGA Reference Number: RC-2014-RN-00655-1

Dear Distributor,

The purpose of this letter is to inform you of a corrective action that HeartSine Technologies Ltd. is introducing in relation to the Pad-Pak/Pedi-Pak non-rechargeable battery and defibrillation electrodes. The Pad-Pak (adult) and Pedi-Pak (paediatric) is an accessory supplied with the HeartSine Samaritan PAD 350P and 500P Defibrillators.

The recall is intended to address an issue where the final seal of the defibrillation electrode pouch was difficult to open.

Aero Healthcare's records indicate that you have received a Pad-Pak/Pedi-Pak device which is affected by this recall.

Issue identified

During testing at Heartsine Technologies Ltd, Belfast, an issue was detected with the seal on the foil pouch with contains the electrodes within the Pad-Pak. On a small number, the final seal on the defibrillation electrode pouch was found to be difficult to open. Testing confirmed that out of 125 pouches tested, 3 were found to be difficult to open. An investigation was able to confirm that the supplier of the electrodes to Heartsine Technologies, Ltd. had made a change to the manufacturing process which meant that an excessive amount of hot melt glue was applied to the final seal of the pouches. They were able to confirm that the change had been made recently and therefore affected a limited number of the electrode pouches.

The following Pad-Pak/Pedi-Pak lot numbers are affected:

A1754, A1795, A1792, A1789, A1802

Corrective action related to the Pad-Pak

To address the issue described in this Recall Action, Aero Healthcare will provide you replacement Pad-Pak's at no charge. We have identified the affected units previously sold to your company and will issue a replacement quantity accordingly. The affected units should be placed in quarantine to await collection by Aero Healthcare.

If you have any questions, please call Aero Healthcare at 1800 628 881.

It is noted that all the affected stock is within your control. If you have further distributed your Pad-Pak's, please notify your customers at once of this communication. Please also provide Aero Healthcare with the customer's contact information so that we can follow-up with the current owner of the device.

This action has been undertaken after consultation with the Therapeutic Goods Administration (TGA)

We appreciate your understanding as we work to ensure that we are providing you with the most up to date and reliable devices you have come to trust.

Sincerely,

Tim Ovenden
Managing Director

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