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Sept 22, 2014

Urgent Device Correction

ZOLL Pro-padz Sterile Multi-Function Electrodes

PROBLEM:

ZOLL Pro-padz Sterile Multi-Function Electrodes part numbers 8900-4012, 8900-4013, 8900-4052-40 and 8900-4055-40 from Lot Numbers: 2114, 1914, 1814, and 1614 have been identified through our routine quality sterility evaluation as being compromised and may be found to be non-sterile.

To date, we have not received field reports of these electrodes resulting in harm to the patient and/or caregiver. Given the potential sterility compromise, users are requested to remove Lot Numbers 2114, 1914, 1814, and 1614 of the part numbers listed above from use.

RECOMMENDED ACTIONS:

The following actions should be taken:

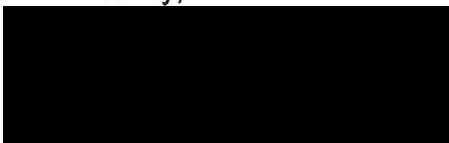
- Alert staff of this issue
- Remove Lot Numbers 2114, 1914, 1814, and 1614 from possible use
- Follow instructions in the Device Correction Response Return form.

CORRECTION:

ZOLL Pro-padz Sterile Multi-Function will be replaced free of charge with new electrodes. We have notified the FDA and appropriate Regulatory Agencies of this corrective action and expect it to be classified as a recall.

We apologize for any inconvenience this may cause you and thank you in advance for your assistance in implementing this corrective action. Our 24/7 technical support numbers 1 (800) 348-9011 or +1 (978) 421-9460 are available to assist users with any aspect of this notice.

Sincerely,



Director Regulatory Affairs