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An Asahi Kasei Group Company

May 28, 2019

Urgent Device Correction
ZOLL Pro-padz® Liquid Gel Radiolucent Electrodes
Part Numbers: 8900-2105-01 and 8900-2106-01
Lot Numbers: 1719, 1719A and 1819

Dear Valued Customer,

ZOLL Pro-Padz Liquid Gel Radiolucent Electrodes may prevent delivery of defibrillation or pacing therapy.

ZOLL Medical Corporation is voluntarily recalling ZOLL® Pro-padz Liquid Gel Radiolucent Electrodes. The ZOLL® Pro-padz Liquid Gel Radiolucent Electrodes are used in conjunction with the ZOLL® R Series, M Series, E Series, and X Series defibrillators. These electrodes are used for cardioversion, non-invasive pacing, ECG monitoring and defibrillation.

We are notifying recipients of ZOLL® Pro-padz Liquid Gel Radiolucent Electrodes that some of the electrodes from lot numbers 1719, 1719A and 1819 may have been assembled incorrectly. There is no visual indication to the end user on the electrodes that the product is not assembled correctly. However, the improperly assembled electrodes will cause the defibrillator to display a "Check Pads" or "Pads Off" message and prevent the defibrillator from delivering therapy.

REQUIRED ACTIONS:

The following actions should be taken:

- Inform users of this problem.
- Remove all stock of part numbers 8900-2105-01 and 8900-2106-01 with lot numbers 1719, 1719A and 1819. *No other lots are impacted.*
- Complete the attached Response Form and return to ZOLL. A ZOLL representative will contact you to coordinate the return and replacement of your electrodes.

CORRECTION:

ZOLL has adequate inventory and will replace the affected lots with correctly assembled electrodes immediately.

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. Avoiding this problem during clinical use is our highest priority. 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,

VP Quality Assurance & Regulatory Affairs



URGENT Device Corrective Action
Customer Response Form for Pro-Padz Radiolucent Electrodes

Part numbers 8900-2105-01 (case of 12) and 8900-2106-01 (single)
Unique Device Identifier DI = 10847946016408 (case) and 00847946016401 (single); PI = Lot 1719A, 1719, 1819

Please locate & contain the product referenced below that was shipped to your facility.

Part Number Ordered	Lot Number	Quantity (In Singles)	Quantity Located	Quantity Utilized/Discarded

- ✓ All unused product must be returned to ZOLL with a completed copy of this form.
- ✓ If you need replacements, make sure to complete Section 4 below.
- ✓ Please complete this form in its entirety and return to regulatoryteam@zoll.com or fax to (978) 421-0038.
- ✓ A ZOLL representative will contact you with instructions to return your affected product.

1. Customer Account Information		
Customer Account Name		Account Number
Ship To Address		
City	State	Postal Code
2. Customer Contact Details		
Individual completing this form (please print)		Title
E-mail Address		Phone Number
3. Product Inventory Status (check all that apply)		
<input type="checkbox"/> Our facility has affected product and we have indicated the quantity <u>located</u> (in singles) in the table above.		
<input type="checkbox"/> Affected product has been <u>utilized/discarded</u> and we have indicated the quantity located (in singles) in the table above.		
<input type="checkbox"/> REPLACEMENTS ARE REQUIRED and we have completed Section 4.		
<input type="checkbox"/> Our facility no longer has the affected lot number as product was internally transferred or distributed/sold and a copy of this corrective action has been provided to the party in possession of the product. To facilitate locating the product, I am providing ZOLL with contact details below.		
Facility/Org:		Address:
Contact Name:	Email:	Phone:
4. Replacement Product		
Ship to Address: (if different from above)		Quantity of Replacements Needed
		(in single qty.) _____
		PO Number (if reqd. by your facility to receive product) _____
Form Completed By		
Print Name	Signature	Date

Please return to regulatoryteam@zoll.com or fax to (978) 421-0038