

## **MEDICAL DEVICE RECALL**

January 26, 2024

Product affected: Tensive Conductive Adhesive Gel, Ref. 22-60

## Lot Number A0623009

Parker Laboratories, Inc. is conducting a voluntary recall of the above product. The reason for this recall is the viscosity of the affected lot is too high. A Health Hazard Assessment has determined that the likelihood of an adverse event associated with the use of the affected products is low; however, delay of procedure may occur and mild patient skin irritation is possible.

Our records show that you have purchased affected product (see attached Recall Response Form for a complete list of affected product and the dates product was shipped to you). Accordingly, please take the following actions necessary for this recall:

- Immediately examine your inventory for the affected product listed in the Recall Response Form (attached).
- Discontinue distribution of any product affected by this recall.
- Promptly email your acknowledgement of receipt of this Recall Notification to Parker at <u>ParkerQA@parkerlabs.com</u>
- Promptly complete the Recall Stock Response Form (attached) and return it via email, mail, or fax to:

Email address: ParkerQA@parkerlabs.com

Fax: 973.276.9510

Phone: 973.276.9500 ext 7107

Mailing address: Parker Quality Representative

4 Sperry Road Fairfield NJ 07004

- If you have further distributed any affected product, please perform a SUB-RECALL to your direct accounts. You may use this Recall Notification and the Recall Stock Response Form (attached) as a basis for your SUB-RECALL letter. If you have any questions or need any assistance with notification of your direct accounts, please contact the Parker Quality Representative using the contact information above.
- Even if you do not have any affected product to return, complete the Recall Response Form and return it to us by email, mail or FAX as instructed above.

Parker Laboratories will make arrangements for you to return any affected product remaining in your inventory. A Return Authorization Number will be provided, and reimbursement/replacement will be arranged when the product is received.



If you have any questions, please email or call Parker Laboratories at:

Email: ParkerQA@parkerlabs.com

Phone: 973.276.9500 ext. 7107 (Parker Quality Representative)

Hours of Operation: Mon-Thurs: 8:30 AM - 5:00 PM / Fri: 8:30 AM - 1:00 PM

Please accept our apologies for any inconvenience you may experience as a result of this recall.

Best regards,

