

September 4, 2018



**URGENT FIELD SAFETY NOTICE**  
**LONE STAR® SINGLE-USE ELASTIC STAYS**

Dear Valued CooperSurgical Customer,

CooperSurgical has issued a Field Safety Corrective Action for 11 lots in the enclosed list on page 3 of its SINGLE-USE ELASTIC STAYS [CooperSurgical part numbers **3314-1G; 3316-1G; 3550-1G**]. The Elastic Stays are a sterile single-use medical device providing retraction to achieve and maintain optimal visualization throughout a variety of procedures.

CooperSurgical is recalling this product due to the possibility that the seal of the sterile pouch may be compromised, thereby increasing the risk of infection. This condition was detected during the inspection of returned merchandise. There have not been any adverse events reported to CooperSurgical due to this potential issue.

A product is acceptable for use if it is visually confirmed that the pouch's seal is intact. As indicated in the Directions for Use (DFU), each package should be handled with care and inspected for damage, including the seal area before use. Inspect the package contents and the sterile seal along the entire periphery of the package. Refer to the table below for examples of acceptable / not acceptable conditions.

<b>ACCEPTABLE</b> <b>(packaging seal with uniform 1/8" seal)</b>	<b>NOT ACCEPTABLE</b> <b>(packaging with void or crooked seal)</b>
	

Our records indicate you have purchased the affected product from CooperSurgical. This recall only affects 11 lot numbers manufactured between April 2018 and July 2018. Please be advised that CooperSurgical has initiated a corrective action to screen finished goods in inventory for potential unsealed pouches. If any

product from the 11 lots is in your possession and has a green label affixed to the outer display box as displayed below, it **is not affected** by this recall action.

### *Green Label Example*



Please discontinue use of the product with any packaging irregularities, quarantine the product, and complete the attached **Acknowledgement and Receipt Form** to arrange for either a product replacement or credit to your account through CooperSurgical. Once completed and returned to CooperSurgical, a Customer Service Representative will contact you with a Return Merchandise Authorization (RMA) number and provide instructions for the return of product to CooperSurgical. If replacements are requested, a replacement order will be placed immediately. If you have no affected stock, please complete and return the enclosed **Acknowledgement and Receipt Form**, in order for us to document receipt of this letter.

The relevant Competent Authorities have been notified of this action. CooperSurgical is committed to high quality, safe and effective products. We apologize for any inconvenience caused by this action and feel free to reach us at 203-601-5200 ext. 3300.

Sincerely,

