CooperSurgical
75 Corporate Drive
Trumbull, CT 06611
(203) 601-5200
FAX (203) 601-9870
Regulatory Affairs & Quality Assurance

September 4, 2018

URGENT MEDICAL DEVICE RECALL NOTIFICATION

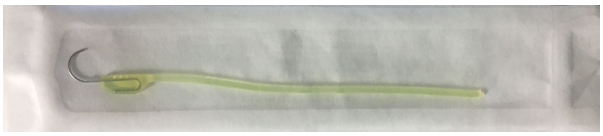
LONE STAR® SINGLE-USE ELASTIC STAYS

Dear Business partner, Chairman of Medical Board, and all relevant Head(s) of Departments,

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.

ACCEPTABLE **(packaging seal with uniform 1/8" seal)**	**NOT ACCEPTABLE** **(packaging with void or crooked seal)**
	

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

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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. If you are a medical facility, it is imperative to notify all the relevant Department Head(s) and the Chairman of the Medical Board, if applicable, of this Field Service Corrective Action.

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,

[redacted]

Peter Niziolek
Product Surveillance Manager

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COOPERSURGICAL® SINGLE-USE ELASTIC STAYS

Affected Lots

Part Number	Description	Lot Number
3314-1G	3mm Elastic Stays	244660
3316-1G	5mm Elastic Stays	245964
		250426
		251395
3550-1G	Dual Lead Elastic Stays	244667
		244883
		244884
		245603
		245973
		246138
		248871

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Acknowledgement and Receipt Form: Response is required

Please complete this form and return in the attached prepaid envelope or fax to **203.601.9870 ATTN: Product Surveillance.** CooperSurgical will arrange for a product replacement or credit after this form has been received.

Customer Account #: _____ Account Name: _____

Street Address: _____ Town, State, Zip Code:_____

Contact Name: _____ Phone Number: _____

Email address: _____

I have read and understand the recall instructions provided in the September 4, 2018 letter. Yes _____ No___

Any adverse events associated with recalled product? Yes _____ No____

If yes, please explain: _____

Affected Product Information: Please check the appropriate boxes below and complete the table if applicable.

☐ We have no inventory within the scope of this recall.

☐ We have the following affected product at our facility and have discontinued use and distribution. We have quarantined the affected product, and will return the following quantities.

Lot Number	Quantity to be Returned

Please select one of the following;

☐ Send replacements

☐ Credit our account

If you have additional questions, please contact a CooperSurgical Product Surveillance representative at **203.601.5200** Ext. **3300** or email us at **recall@coopersurgical.com**. Adverse reactions or quality problems experienced with the use of this product may be reported to the respective Competent Authority's Adverse Event Reporting program either online, by regular mail or by fax.

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FOR DISTRIBUTORS ONLY:

Customer Account #: _____ Account Name: _____

Contact Name/Title: _____ Phone Number: _____

Email address: _____

Affected Product Information: Include information that is applicable for affected product.

I have read and understand the recall instructions provided in the September 4, 2018 letter. Yes __ No__

I have checked my stock and have quarantined inventory consisting of _____units_____boxes

Lot/Serial Number shipped to Customer : _____ Quantity Shipped:_____

I have identified and notified my customers that were shipped or may have been shipped this product by _____
_____(Specify date and method of notification)

or

Please notify the attached is a list of customers who received/may have received this product.

Signature of Receipt: _____

PLEASE FAX COMPLETED RESPONSE FORM TO: **203.601.9870** ATTN: **Product Surveillance**