liflfenin9- .. snddowemgdJfionll'

URGENT VOLUNTARY RECALL NOTICE
PADLOCK CLIP DEFECT CLOSURE SYSTEM

February 1, 2019

ATTN: Materials Management

Recall Regarding: US Endoscopy Padlock Clip defect closure system (C910001)

Dear Valued Customer:

US Endoscopy is implementing a voluntary recall of the Padlock Clip defect closure system (Product Number C910001). Our records indicate that your facility has received product *trom* the affected lots 1814568, 1814569, 1815200, 1815592, 1816056, 1817174, 1817810, 1818187, 1818596, 1819180, 1819181, 1819407, 1819793, and 1820177.

Description of the product: The Padlock Clip is indicated for use in flexible endoscopy and for the compression of tissue in the gastrointestinal tract, for hemostasis or for treating lesions of the wall of gastrointestinal organs.

Description of the problem: US Endoscopy received a single report of an esophageal laceration during a patient procedure in which our Padlock Clip defect closure system (C910001) was one of the medical devices utilized. We are uncertain if the laceration is the result of our Padlock Clip defect closure system. The patient procedure included tour (4) endoscopie insertions and withdrawals; bloed was initially noted during the second endoscopie withdrawal. The patient was monitored and subsequently discharged with no additional issues.

Upon inspection of the returned device, US Endoscopy identified that a small piece of the plastic housing was not properly seated/flush. If not flush, this could result in a laceration to the surrounding tissue during withdrawal of the endoscope. We were unable to determine the extent of units affected. Production and process changes have been implemented to ensure this issue does not recur. Please note that any individuals who have the clip implanted are not affected by this field action.

User action required: Please ensure the following steps are completed:

1. Quarantine affected Padlock Clip defect closure systems (C910001).
2. Complete the Medical Device Recall Response Card included with this Customer Notification Letter. US Endoscopy can assist should you have any questions while completing the Card.
3. Return the completed Medical Device Recall Response Card to Cindy Perpar via email to cperpar@usendoscopy.com or via fax to 440-639-4495. US Endoscopy will coordinate return of your affected Padlock Clip defect closure systems and issuing replacement product upon receipt of the completed Recall Response Card.

We apologize for any inconvenience this matter may cause you, and as always, US Endoscopy is dedicated to the support of our products and valued Customers. lf you have any questions regarding this matter, please contact Cindy Perpar at 440-358-6051.

PLEASE RETAIN THIS LETTER FOR VOUR RECORDS

MEDICAL DEVICE RECALL RESPONSE CARD
PADLOCK CLIP DEFECT CLOSURE SYSTEM

Recall Regarding: US Endoscopy Padlock Clip defect closure system (C910001)

Affected Lots: 1814568, 1814569, 1815200, 1815592, 1816056, 1817174, 1817810, 1818187, 1818596, 1819180, 1819181, 1819407, 1819793, and 1820177.

D We acknowledge the receipt of this recall notification and understand its content. Next, complete a) orb) below:

D a) We have no stock of the listed lot number(s), or

D b) We do have stock of listed lot number(s), tor return to US Endoscopy:

Lot Number(s)	Quantity for Return

US Endoscopy requests that you:

1. Quarantine the affected Padlock Clip defect closure systems (C910001).
2. Please complete this Medical Device Recall Response Card, which was included with the Customer Notification Letter. US Endoscopy will coordinate return of your affected Padlock Clip defect closure systems and will issue replacement product upon receipt of the completed Recall Response Card. US Endoscopy can assist you should you have any questions while completing the Card.

Return the completed Medica! Device Recall Response Card to Cindy Perpar via email to cperpar@usendoscopy.com or fax to 440-639-4495. This Card must be completed and returned in order to return on-hand product and receive replacement Padlock Clip defect closure system(s).

Name and Title (print) _____ Phone Number / Email _____

Signature and Date _____ Facility Name and Address _____

PLEASE RETAIN A COPY FOR YOUR RECORDS