



December 19, 2018

**URGENT: MEDICAL DEVICE RECALL
 PROMPT RESPONSE REQUIRED**

ATTENTION:

Risk Management and Recall Administration

Our records indicate that you have received some of the affected products listed below.

Description of the problem

Cook considers the safety and satisfaction of our customers a top priority. We appreciate your time and attention in reading this important notice.

Cook has received complaints for difficulty in sliding down the retention mechanism on Entuit® Secure Gastrointestinal Suture Anchor Set manufactured with a specific extension spring lot. Therefore, Cook is initiating a voluntary recall of the 39 lots of Entuit® Secure Gastrointestinal Suture Anchor Set that were manufactured with the affected extension spring lot.

Potential adverse events that may occur if an affected product is used include delayed or prolonged procedure, additional intervention to place more devices, and prolonged hospitalization.

Details about the affected products

PRODUCT BRAND NAME	REFERENCE PART NUMBER (RPN)	ORDER NUMBER	LOT NUMBER
Entuit® Secure Gastrointestinal Suture Anchor Set	GIAS-SRM-2	G35569	8144390, 8159665, 8173295, 8204594, 8261263, 8294836, 8308856, 8331166, 8395981, 8459751, 8471244, 8511162, 8535303, 8541938, 8574041, 8582863, 8597539, 8541938X, 8582863X
	GIAS-SRM-3	G35570	8056941, 8135292, 8165522, 8228910, 8261265, 8293447, 8331165, 8357394, 8389427, 8395982, 8445405, 8471250, 8483543, 8511203, 8556989, 8557006, 8564659, 8622758, 8628912, 8663134



Intended use for the affected products

PRODUCT BRAND NAME	INTENDED USE
Entuit® Secure Gastrointestinal Suture Anchor Set	The Entuit Secure Gastrointestinal Suture Anchor Set is intended for anchoring the anterior wall of the stomach to the abdominal wall prior to the introduction of interventional catheters.

Action to take

1. Examine your inventory immediately to determine if you have affected product(s), and quarantine affected product(s). Immediately cease all distribution and use of these products.
2. Return the affected product(s) to Cook Medical with a copy of the Acknowledgement and Receipt Form to receive a product credit.
NOTE: Unaffected products that are returned will not be credited.
3. Please complete the Acknowledgement and Receipt Form within **5 business days** of receiving this letter. **Even if you do not have affected product(s) on hand**, you must still complete the Acknowledgement and Receipt Form and return it via fax (812.339.7316) or email (FieldActionsNA@CookMedical.com).
4. Immediately report adverse events to Cook Medical Customer Relations by phone at 800.457.4500 or 812.339.2235, Monday through Friday between 7:30 am and 5:00 pm (Eastern Time) or by email to CustomerRelationsNA@CookMedical.com.

Adverse events or quality problems experienced with the use of this product may also be reported to the FDA.

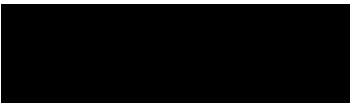
- Visit <http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm> to obtain a form to fax or mail.
- Call the FDA at 800.FDA.1088.

Transmission of this notice

This notice must be shared with appropriate personnel, including down to the user level, within your organization or with any organization where the potentially affected devices have been transferred.

This action is being taken with the knowledge of the Food and Drug Administration.

We recognize that this situation is a potential disruption to your normal operations, and we sincerely apologize. Thank you for your immediate assistance in this matter. If you have any questions or concerns, please contact Cook Medical Customer Relations at 800.457.4500 or 812.339.2235. We look forward to your response.



Larry D. Pool
Director, Post Market
Cook Incorporated



URGENT: PROMPT RESPONSE REQUIRED

Acknowledgement and Receipt Form

You are required to fill out and return this form. Please return it within 5 business days of receipt, even if you do not have any of the affected product(s).

Please complete the following information regarding the recall on the Entuit® Secure Gastrointestinal Suture Anchor Set.

Your customer information

Customer Account Number:	Customer Name:	
Street Address:	City:	
State, Zip Code:	Department:	Phone:
Form Completed By (Printed Name, Signature):		Date:

Actions you have taken

- I have received the letter titled "URGENT: MEDICAL DEVICE RECALL" regarding the Entuit® Secure Gastrointestinal Suture Anchor Set, and I understand the instructions in the letter. Yes No

Affected product information

Please list the quantity of affected product at your facility to be returned, or write "none" if the affected product is no longer in your inventory or is no longer with your customers.

QUANTITY	PART NUMBER	LOT NUMBER

Additional actions for distributors

Share the letter "URGENT: MEDICAL DEVICE RECALL" with appropriate personnel within your organization or with any organization where the potentially affected product(s) have been transferred.

Please confirm the following:

- I have notified my customers of the recall. Yes No

Returning this form and affected product(s)

Upon completion of this form, please return it to the Cook Medical Customer Relations department via fax or email.

Fax: 812.339.7316 Email: FieldActionsNA@CookMedical.com

For information regarding the recall, medical questions, or to report adverse events, contact Cook Medical Customer Relations at 800.457.4500 or 812.339.2235.

Return affected product(s) and send this form to this address:

Cook Medical
 ATTN: Return Good/Recall # FAIP-2018-009
 400 Daniels Way
 Bloomington, IN 47404