COOK®

**Cook Medical Europe**
O'Halloran Road,
National Technological Park,
Limerick, Ireland.
Phone: + 353 61 334440
Fax: + 353 61 334441

# Urgent Field Safety Notice

**Commercial name of the affected product:** Entuit® Secure Gastrointestinal Suture Anchor Set
**Manufacturer :** Cook Incorporated,
**Cook Reference Number:** 2018FA0010
**Type of action:** Field Safety Corrective Action (FSCA)

---

Date: 13 Dec 2018

Attention: Chief Executive / Risk Management / Purchasing

**Details on affected devices:**

| 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 |

**Description of the problem:**
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.

**Advise on action to be taken by the user:**

1. Immediately collect all remaining affected products as per the specified lot listing from your inventory.

2. Please complete the enclosed Customer Response Form. Where product is indicated as being returned, our Customer Services department will contact you to organize the return and issue you

 

with the relevant Returns Authorization number. Please include contact details on the Customer Response form.

Product should be addressed to:
Cook Medical EUDC
Robert-Koch-Straße, 2
52499 Baesweiler
GERMANY

Credit will be provided for the returned affected products where applicable.

3. Send the Customer Response Form via email to European.FieldAction@CookMedical.com or alternatively by fax to Cook Medical marked for the attention of European Customer Quality Assurance (fax number +353 61239294). Do not enclose the response form with the returned product.

4. Please report any adverse events to Cook Medical by contacting our Customer Support Department.

**Transmission of this Field Safety Notice**:
This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (If appropriate)

Please transfer this notice to other organisations on which this action has an impact. (If appropriate)

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. (if appropriate)

**Contact reference person:**

Larry Pool
Post Market Director
Cook Incorporated
50 Daniels Way, PO Box 489, Bloomington, IN 47402, United States

The undersign confirms that this notice has been notified to the appropriate Regulatory Agency.

Should you have any questions, please feel free to contact us for more information (e-mail: European.FieldAction@CookMedical.com, phone +353 61 334440).

Larry Pool
Post Market Director

 

COOK®


**Cook Medical Europe**
O'Halloran Road,
National Technological Park,
Limerick, Ireland.
Phone: + 353 61 334440
Fax: + 353 61 334441


# FIELD ACTION CUSTOMER RESPONSE FORM

**Field Action reference no.: 2018FA0010**
**Affected device:** Entuit® Secure Gastrointestinal Suture Anchor Set

**Please indicate the following:**

Customer Number (As Indicated on the attached product list): _____

Customer Name: _____

Street Address: _____

City, ZIP: _____

Completed by: _____

Department: _____

Phone Number: _____
(Please Print)

**Please indicate which of the following applies to your facility:**

☐ None of the affected product remains in our inventory

***Product(s) implanted:* ☐ Yes ☐ No

☐ We are returning our remaining inventory, please see details listed below

***Choose account action for returned product(s):* ☐ Credit ☐ Free of charge replacement

***Proforma Invoice Required for Return of Product(s):* ☐ Yes ☐ No

**If you are a distributor, have your customers been notified of this Field Safety Corrective Action?

☐ Yes ☐ No

If you are returning any affected product, please indicate the part number, lot number and quantity:

| Product Part Number | Product Lot Number | Quantity |
|---|---|---|
| | | |
| | | |
| | | |
| | | |
| | | |

Signed: _____ Date: _____

Please return the completed Customer Response Form to by e-mail to European.FieldAction@cookmedical.com or by fax to + 353 61 239294.