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<Name and Address of Hospital>

<Date>

TO: WHOM IT MAY CONCERN

CC: Chairman Medical Board and relevant Head of Department

Attached is a Field Safety Notice pertaining to the Geenen Sof-Flex Pancreatic Stents (GPSO-SF-5-5)

Please note that the Lot Number of the product affected is stated below:

Affected Lot Number: W4043729.

GPSO-SF-5-5 products (lot W4043729), was only distributed in the United States.

The affected product lot was only distributed in the United States, it was not imported nor distributed in Singapore.

Should you have any questions, please contact Cook Medical for more information.

Please use [SNG-RegulatoryAffairs@CookMedical.com](mailto:SNG-RegulatoryAffairs@CookMedical.com)



**URGENT: MEDICAL DEVICE RECALL**

Affected Product: Geenen Sof-Flex Pancreatic Stent (GPSO-SF-5-5)

Date: [DATE]

ATTENTION: [Customer Name]

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Geenen Sof-Flex Pancreatic Stents are used to drain obstructed pancreatic ducts.

**Reason for the Voluntary Recall:**

The aforementioned product is being recalled because a GPSO-SF-5-5 was manufactured incorrectly and instead was made to the specifications of a GPSOS-SF-5-5. The device was made with two flaps instead of four, and the drainage holes were made at quarter turn intervals instead of half turn intervals at the distal end of the device. Cook Medical has received 1 complaint related to the problem. The device labeling indicated a GPSO-SF-5-5 and the package contents were a GPSOS-SF-5-5. Cook Medical is initiating a voluntary recall of the lot in distribution.

**Risk to Health:**

The most likely potential consequence that may occur as a result of the device being mislabeled is: Loss of part or all of device function; nuisance to patient or end user. The mislabeling can be recognized by visually examining the device. The GPSO-SF-5-5 is manufactured with four flaps versus the GPSOS-SF-5-5 which is manufactured with two flaps.

**Actions to be taken by the Customer/User:**

1. Please review the attached list of affected lot numbers shipped to your account and quarantine any affected product that remains unused. If you are a distributor and the products have been distributed, contact your customer(s) and direct them to quarantine any affected product.
2. Immediately collect and return all unused affected products at one time to Cook Medical as soon as possible. Affected product should be returned to:  
Cook Medical  
Attn: Return Goods Department – 051-R  
400 Daniel's Way  
Bloomington, IN 47404
3. Please complete the attached Recall Return Response form and send to Cook Medical. This form may be sent via fax using the **fax number: 812-339-7316** or scanned and emailed to [FieldActionsNA@cookmedical.com](mailto:FieldActionsNA@cookmedical.com). Replacement product(s) or account credit will be issued to your facility upon receipt of this form with the completed information.

Product and Distribution Information Table					
Product Names, Unique Device Identifier (if applicable)	Manufacturer's Product Number/Catalog number	Lot/Serial Number	Manufacturing/Distribution Dates	Expiration Date (MM/DD/YYYY)	Quantity

Thank you for your immediate attention to this matter. We apologize for any inconvenience. Should you have any questions, please contact the Customer Relations Department at Cook Medical for more information. Please use [CustomerRelationsNA@cookmedical.com](mailto:CustomerRelationsNA@cookmedical.com), or call us toll free – 1-800-457-4500, press 4, then enter extension 15-2146. Monday through Friday, 8:00AM to 4:30PM, Eastern Time.

Sincerely,



Scottie Fariole  
Manager, Regulatory Reporting  
Cook Medical

EXAMPLE