PillCam® Express Delivery Device
Urgent Product Recall

[Customer Name]
[Address]
[Town and Zip Code]

[Place, Date]

Dear Valued Customer,

Our records indicate that you have received this product:

PillCam® Express Delivery Device, part number FGS – 0366 (Singles) or FGS-0367 (3-Pak)

On behalf of Given Imaging [Distributor Name] is conducting a voluntary recall of the PillCam® Express Delivery Device

Please read this important information packet in its entirety. The enclosed directions require action on your part.

Given Imaging has received reports of failure of the PillCam® Express Delivery Device. As a result of field reports and data discussed internally, a decision was made to voluntarily recall this product, and cease its further commercialization or distribution. The defects occurred during normal use, but were also on occasion observed when the product was used in a manner that was not supported by its design specifications and tolerances. Given Imaging felt, and medical consultants agreed, that this decision would be in the best interests of patient safety and product effectiveness.

The PillCam® Express Delivery Devices must be immediately removed from use.

In order to ensure that the devices noted above are retrieved from your inventory, we request that you locate the devices as soon as possible, remove them from use and return all of them to [Distributor Name] according to the instructions on the attached Recall Confirmation Sheet. We also require information on the devices that have already been used so that we can reconcile all distributed devices. Please follow the enclosed directions carefully. If you forwarded these devices to other facilities, please forward this information to them immediately.
It is imperative that all end users of the PillCam® Express Delivery Device be notified. We apologize for any inconvenience this may cause. As always, Given Imaging and [Distributor Name] strive to provide the highest quality products and service to our valued customers.

This voluntary recall is being conducted with the knowledge of the FDA, the German BfArM and the [Name of local authority].

If you have any questions or require additional information, please contact [Distributor Name] at the number listed below.

[Telephone number of Distributor]

Sincerely,

The [Distributor Name] Management Team

Attachment: Delivery Device Recall Confirmation

Please complete the following and return it to {Name of Distributor} per the instructions at the bottom of this form. All unused devices should be returned to {Name of Distributor}.

Please fax this completed form to {Fax # of Distributor}. No cover sheet is necessary.

OR

Scan and e-mail to {E-mail address of Distributor}.

PillCam® Express Recall Confirmation for:

Customer Number: {Customer Number} ***Customer Name:*** {Customer Name}

1. All unused PillCam® Express Devices at the facility have been retrieved from all our locations within the facility, physically separated from products available for use, and removed *(check one)*:

❒ YES ❒ NO Unused Product ❒ NO, explain:

_____

2. Fill in the quantity of these devices remaining at the facility.

   Our records indicate that the following **PillCam® Express Devices** affected by this voluntary recall were shipped to the facility:

Product	***No. of Devices Shipped***	***Quantity of Unused Remaining at Facility***
PillCam® Express FGS – 0366 (Singles)	{#}	
PillCam® Express FGS-0367 (3-Pak)	{#}	

(If you have used all of either type of the affected devices please indicate "0" remaining for that type.)

If you have unused devices, we will provide you with material and instructions to return the devices to us at no cost to the facility once we receive this information. To receive credit for any unused devices, they will need to be returned.

3. The following is a **REQUIRED FIELD**. **Confirmation completed by:**

_____	_____	_____	_____
Printed name	*Title*	*Signature*	*Date*