38, rue de l'Université - 69007 Lyon
Tél. +33 (0)4 72 61 85 66
Fax. +33 (0)4 72 61 92 75
info@latitudemedical.com
www.latitudemedical.com

HOPITAUX CIVILS DE COLMAR
39 avenue de la liberté
68024 COLMAR

Lyon, le 20 octobre 2011

A L'attention de Messieurs les Ingénieurs médicaux :
- M. Michel DIEHL
- M. Eric PERRIN
- M. Vincent CHAPIN

A l'attention de M. Daniel RONCALEZ (pharmaco-viligance)

Messieurs,

Vous avez reçu le 30 septembre une boîte de gaines pour manométrie ano-rectale (offerte pour l'installation du matériel de manométrie haute résolution)

- référencée : MSS-3599
- lot n° F1127303UA

Nous avons pour mission de procéder au retrait de ce lot suite à **une procédure de rappel** lancée par le fabricant (voir courrier joint).

Ainsi, les gaines ne doivent plus être utilisées et retournées à notre attention dès que possible accompagnées de la fiche ci-jointe.

Nous vous prions de bien vouloir nous excuser pour cette gêne occasionnée et nous tenons à votre disposition pour tout renseignement complémentaire.

Nous vous prions d'agréer, Messieurs, nos sincères salutations

Sabine FREVILLE

LATITUDE médica
SARL au capital de 7500€
38. rue de l'Université
69007 LYON
490 155 488 RCS LYON

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RAPPEL VOLONTAIRE

CLIENT : HOPITAUX CIVILS DE COLMAR

Produit en votre possession : MSS – 3599 – lot F1127303UA

❒ oui ❒ non

Afin de vous établir un avoir sur les gaines non utilisées, nous vous remercions de bien vouloir les reporter sur le tableau ci-dessous et nous les retourner à l'adresse suivante :

LATITUDE MEDICAL
38 rue de l'Université
69007 LYON

PRODUIT	***N° de lot***	***Date d'expiration***	***Nbre de gaines totales***	***Nbre de gaines utilisées***	***Nbre de gaines retournées***

(Si vous avez utilisé toutes les gaines, merci de remplir par un "0" la colonne Nbre de gaines retournées et faxer cette fiche au 04 72 61 92 75).

Date :

Nom et qualité du signataire :

Given Imaging, Los Angeles
5757 W. Century Blvd..
Suite 660
Los Angeles, CA 90045
'USA
Phone: +1 (310) 641-8492
Fax: +1 (310) 872-5558

Urgent Product Recall
1st Notice

Customer Name:
Attention: Risk Management
Address:
City:
Zip Code:
Country:

October 12, 2011

Dear Valued Customer,

Please read the important information enclosed in this packet. Our records indicate that you have received this product: **AR ManoShield, part numbers MSS-3599.**

Please be advised that a decision was made to voluntarily recall this product and cease its further commercialization or distribution until such time as reported defects can be fully evaluated and rectified. Through normal testing pinholes have been discovered in a small percentage of the product. Given Imaging has determined, and medical consultants have agreed, that the voluntary recall would be in the best interests of patient safety and product effectiveness.

The AR ManoShield must be immediately removed from use.

The enclosed directions require action on your part.

In order to ensure that the devices noted above are removed from inventory, we request that you locate the devices as soon as possible and remove them from use. We will 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 AR ManoShield be notified.

We apologize for any inconvenience this may cause. As always, Given Imaging strives to provide the highest quality products and service to our valued customers.

If you have any questions, please contact me via the information listed below.

Best Regards,

Karla Guerrero
Quality Assurance Manager
Given Imaging, Los Angeles
Telephone: +1 (310) 641-8492ext.2138
Fax: +1 (310) 872-5558
Email: karla.guerrero@givenimaging.com

Given Imaging, Los Angeles
5757 W. Century Blvd..
Suite 660
Los Angeles, CA 90045
'USA
Phone: +1 (310) 641-8492
Fax: +1 (310) 872-5558

AR ManoShield Device Recall Confirmation for:

Customer Number: ***Customer Name:***

Items currently in inventory have been removed *(check one)*:

❒ YES ❒ NO ❒ Not Applicable

To receive credit for any unused devices, the unused devices will need to be returned. Please complete the following and return per the instructions at the bottom of this form:

1. Fill in the quantity of these devices that you have remaining.

Our records indicate that you were shipped the following **AR ManoShield** affected by this voluntary recall:

Product	***Batch No.***	***Exp Date***	***No. of Devices Shipped***	***No. of individual units already used***	***No. of Devices already returned to Given Imaging***	***No. of individual units remaining at Facility***

(If you have used all affected devices, please indicate "0" remaining at your facility and fax or e-mail this form as directed below.)

If you have devices to return, we will provide you with material and instructions to return the devices to us once we receive this information.

2. The following is a **REQUIRED FIELD.**

Recall confirmation completed by:

_____	_____	_____	_____
printed name	*title*	*signature*	*date*

Please fax the completed form to +1 (310) 872-5558. No cover sheet is necessary.
OR
Scan and e-mail to karla.guerrero@givenimaging.com.