Advanced Medical Solutions
(Plymouth) Ltd.

Advanced Medical Solutions (Plymouth) Ltd
Western Wood Way,
Langage Science Park,
Plympton, Plymouth,
Devon, PL7 5BG, UK
Web : www.admedsol.com

Field Safety Notice

Date issued: 3rd March 2017

Affected products

Product name: LiquiBand® FIX8™
Product code: FX001

Description of the situation

Dear valued LiquiBand® FIX8™ user,

Following further clinical evaluation by Advanced Medical Solutions (**AMS**), with effect from May 2015 the indications for use of the LiquiBand® FIX8™ device (**Product**) were extended from "laparoscopic surgical repair of inguinal hernia, achieved through the fixation of polypropylene or polypropylene / polyester combination hernia mesh to the abdominal wall" to "laparoscopic repair of abdominal hernias, achieved through the fixation of prosthetic mesh to the abdominal wall and the approximation of peritoneum" (**Extended Claims**). During a recent routine technical file audit by our Notified Body (BSI), they confirmed that more data was required to support these Extended Claims.

Risk to health

As Patient Safety is a high priority for AMS, additional clinical data, a review and statement by the field expert in respect of that data, and risk assessments by both AMS and the field expert have already been provided to BSI for review. The following information is consistent with the additional data provided to BSI in respect of the Extended Claims:

- Post Market Surveillance data collected by AMS shows no evidence of adverse events relating to the Extended Claims; and
- the field expert's review of the current clinical data and our risk assessment concluded that the Product is suitable for the Extended Claims and the risk to the patient and user is low.

Please note that until BSI has completed a review of this additional data, we need to communicate to our users of the Product in all European CE-Mark territories that the Extended Claims are under review and, whilst this review takes place, we will only release Products to customers under the original indications for use.

Description of the temporary change

AMS will be temporarily removing revision 03 of the Instructions for Use (**IFU**) from use and re-introducing revision 01. As a result, the following sections of the IFU will be affected:

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	Extended indications under review	Original indications
IFU	**DRM 06 0528 revision 03**	**DRM 06 0528 revision 01**
Indications for use	• The LiquiBand® FIX8™ device is intended for use in laparoscopic repair of abdominal hernias, achieved through the fixation of prosthetic mesh to the abdominal wall and the approximation of peritoneum.	• The LiquiBand® FIX8™ HMF device is intended for use in the laparoscopic surgical repair of inguinal hernia, achieved through the fixation of polypropylene or polypropylene / polyester combination hernia mesh to the abdominal wall.
Precautions	• There is only limited clinical data for mesh other than polypropylene and titanium coated mesh. Bench tests have demonstrated suitable compatibility with meshes made from polyester and polyvinylidene fluoride (PVDF).	• There is only limited medium to long term clinical data available for the safe use of this device for the closure of the peritoneal sac. • There is only limited clinical data to support the safe use of this device for the fixation of polyester hernia repair meshes. Bench tests have demonstrated suitable compatibility and performance.

Required actions regarding the use of the Product

- No corrective action needs to take place for patients who received a treatment according to the Extended Claims.
- There is no physical action required regarding any Products you may have in stock. Please disregard revision 03 of the IFU found in the Product packaging and refer to revision 01 of the IFU which is attached to this notice.
- No action is required for any future shipments of the Products as they will be shipped with revision 01 of the IFU until further notice.

Required actions regarding this Field Safety Notice

- Please ensure that all those who need to be aware of this notice within your organisation receive a copy of this notice.
- Please transfer this notice to any additional people or organisations who also need to be notified.
- As soon as possible, and **no later than 14 days after receipt of this notice**, you should complete the attached form and return it to AMS either by post or by email to the addresses stated on the form.

Contacts

AMS sincerely apologises for any inconvenience caused by this Field Safety Notice. We assure you that we will contact all customers directly and in a timely manner to communicate an update to the

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IFU in respect of the Extended Claims once the review by our Notified Body is complete. In the meantime, please do not hesitate to call your current AMS representative or contact us by email (Regulatory.Plymouth@admedsol.com) if you have any further questions regarding this notification.

The undersigned confirms that this notice has been notified to the appropriate Regulatory Agencies.

[redacted]

For and on behalf of Advanced Medical Solutions (Plymouth) Limited

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Field Safety Notice: Confirmation of receipt form

Date issued: 3rd March 2017

Affected products

Product name: LiquiBand® FIX8™
Product code: FX001

Customer information

I confirm receipt of this Field Safety Notice and that the information has been communicated to all relevant parties.

Distributor Name and Address _____

Hospital / Location _____

Name and Position _____

Contact Email _____

Contact Number _____

Signature _____

Date _____

This form is to be returned **no later than 14 days after receipt of this notice**.
By post to: Advanced Medical Solutions, Western Wood Way, Langage Science Park, Plympton, Plymouth, Devon, PL7 5BG, UK. For the attention of: Rose Guang – Group QA/RA Director.
By e-mail to: Regulatory.Plymouth@admedsol.com.