Filed Safety Advisory Notice
LifeSeal Kit

LifeSeal Kit should not be use during J-pouch procedure.

Date: 21 Feb 2018
Product affected
Product name: LifeSeal Kit
Product code: LB0075LS & LB0085AP & LB0090AP

Description of the situation
Dear customer,

As you were notified by email on January 26, 2018, LifeSeal Pivotal study has recently been placed on hold.

While the assessment of the study by the DSMB is still on going, an initial review of DSMB blinded data set indicated a difference in anastomotic leak rates depending on the type of anastomosis. Patients with a J-Pouch had a significantly higher event rate (47%) than those with an end-to-end or side-to-end anastomosis. Events include Serious Adverse Events reported by the investigators as anastomotic leaks and intra-operative leaks reported by investigators during surgery.

As a precaution and until a full investigation is completed, LifeBond instructs users not to use LifeSeal as an adjunct for sealing J-pouch staple lines.

Starting now and after receipt and review of the final DSMB recommendations in March LifeBond will conduct an investigation to better understand the reason for an increased event rate in J-pouch procedures.

LifeBond will notify the relevant Regulatory authorities as required.

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We kindly ask you to fill in the response form enclosed and send it back to us on Christian@life-bond.com or fax **+972-4-6373878.**
The form will be a confirmation that your site has recived this letter.

Please pass this letter to the relevant personnel whitin your organization, if applicable.

We apologize for any inconvenience this notice may cause.

Do not hesitate to contact us if you have further questions.

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26/2/2018

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RESPONSE FORM

We confirm receipt of the letter

Hospital	Name	Telephone no.:	E-mail:

Signature: _____

Date: _____

Please send the form by fax to 972-4-6373878 or by email to Christian@life-bond.com