URGENT: Field Safety Notice

February 10, 2015

Affected Devices: **Zip® Surgical Skin Closure Devices**

Customer Name:

Customer Address:

Dear Valued Customer:

ZipLine Medical has identified a potential sterility risk associated with Zip® 16 Surgical Skin Closure Devices manufactured between June 2014 and January 2015. This notification details the issue, any potential risks, and required actions to take if the problem described below is encountered.

Affected Units:

The following lot numbers may be affected per this notification:

Product Name:	Zip® 16 Surgical Skin Closure Device
Model Number:	PS1160
Lot Numbers:	**1002539, 1002719, 1002887, 1003054**

According to our records, you have received Zip® 16 devices from the above lot number. If the devices from this lot number have been further distributed, please immediately inform any entities of this notice. In addition, please provide ZipLine with a record of all locations receiving devices from any of these lots by e-mailing Customer Service at customerservice@ziplinemedical.com.

Issue:

The manufacturer's seal located at the bottom of the Zip® pouch may not be sealed.

Potential Risk:

Product contained in an unsealed pouch may not be sterile. Use of the product could potentially result in infection of the incision or wound site.

ZipLine Medical, Inc. | 747 Camden Avenue Suite A | Campbell, CA | 95008
Tel 1.888.326.8999 | Fax 1.888.265.0669 | Email customerservice@ziplinemedical.com | Web www.ziplinemedical.com

Required Action:

Please quarantine your inventory immediately and examine the affected lots for complete pouch seals. Any product found with an incomplete seal should be destroyed or returned to ZipLine Medical. Please complete the enclosed response form as soon as possible, even if you no longer have stock of the lot numbers subject to this correction. This information is required to reconcile the inventory. Please contact Customer Service at customerservice@ziplinemedical.com to coordinate any product returns, replacement stock, or credit notes.

The applicable Competent Authorities have been notified of this action. Any adverse events occurring from use of this product, and/or quality problems should be reported to the Competent Authority.

Your prompt attention is requested to prevent any patient harm. We recognize the inconvenience this may cause and your cooperation and support in this important matter is greatly appreciated. Please do not hesitate to contact customer service with any questions.

Sincerely,

Melissa Guerrero

Director, Quality and Regulatory Affairs

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