ZIEN Medical Technologies

August 18, 2015

2500 South State St. STE D240
Salt Lake City, UT 84115

To: PenBlade, LLC
370 South 300E
Salt Lake City, UT 84111

URGENT PRODUCT RECALL

Affected Devices: PenBlade Safety Scalpels, Model numbers PB-M-10, PB-M-11P, PB-M-15

(Certified Mail/Return Receipt Delivery)

Dear PenBlade:

ZIEN Medical Technologies has identified a possible risk associated with shipping damage that can potentially breach the sterile packaging of all PenBlade product manufactured between September 2014 and July 2015. We are conducting a voluntary recall to remove all product manufactured during this time period. This recall notification details the issue, any potential risks, and recommended steps for users to take if they have the above-referenced affected product. A representative label for the affected products is attached at the end of this document.

Affected Units:

PenBlade Safety Scalpels, Models PB-M-10, PB-M-11P, and PB-M-15, manufactured between September 2014 and July 2015, and shipped between those dates, are potentially affected by this shipping damage. Our records indicate that we have provided you with, or you have purchased, affected PenBlade devices. In the event you no longer own or control the PenBlade product indicated in our records, please immediately provide a record of any change in device location by emailing this information to ZIEN Medical's Sr. Management at tim.nieman@zienmedical.com or by calling 385-646-4419.

Issue:

During our regular quality inspection, it was discovered that shipping damage had occurred to a number of individual devices that created a potential for cracks to form in the sterile packaging that may allow a breach of the package's sterile barrier. This damage may not be easily detected or seen.

ZIEN has not received any complaints of injury or infection associated with compromised sterile packaging. However, it is possible that use of a non-sterile product may introduce microbes and increase the risk of post-procedural infection. Accordingly, if one or more of your patients has undergone a procedure using this product you should make a determination as to what, if any, medical actions are necessary regarding such patients.

Actions to be taken:

1) Immediately cease any further use of affected product, remove it from your inventory, and quarantine it until it is shipped back to us.

2) Call ZIEN Medical at 385-646-4419, to obtain a Returned Goods Authorization so that you may return the product at no charge to you. ZIEN will issue a credit or replacement to your facility for any returned product.

3) In addition, if you have further distributed product, please identify your customers, notify them at once of this product recall, and appropriately document your notification process. Please also issue Returned Goods Authorization so that they may return the product to you wherein ZIEN can retrieve it upon its return. Notification to your customers may be enhanced by including a copy of this recall notification letter.

This recall is being made voluntarily and will be communicated with the US Food and Drug Administration (FDA), so it is important for you to document, in writing, all of your actions regarding this recall as they may be audited by the FDA.

ZIEN regrets any inconvenience caused by this recall and appreciates your prompt cooperation in addressing this situation. Please do not hesitate to contact me directly at 385-646-4419 or at tim.nieman@zienmedical.com for any additional information concerning this matter.

Sincerely,

[redacted]

President, ZIEN Medical Technologies

Attachment: Representative PenBlade Label