



September 25, 2007

RISK MANAGEMENT / REGULATORY

Address

Address

Address

PHONE 978.232.9997

FAX 978.232.9998

WEB [www.axyamed.com](http://www.axyamed.com)

**SUBJECT: URGENT-PRODUCT RECALL**  
**Axya Bone Anchors & Kits**

To Whom It May Concern:

Axya Medical has received reports of breached packages in some sterile bone anchor products. Some products packaged in sterile pouches have been found with holes in the pouch after shipping, therefore compromising the sterility of the device. As a result of these reports, Axya Medical has decided to voluntarily recall the affected lots. This recall affects only anchors that are packaged in pouches.

The affected lot numbers are listed in the attached table.

Our records indicate your facility has received some of the affected lot(s). We are requesting you immediately discontinue use of the affected products and return any unused affected products to our facility. Attached to this letter, you will find a Questionnaire and Return Instructions. Please complete the Questionnaire and return it as soon as possible.

If you are an Axya Medical distributor of the subject device, it is required that you notify any and all accounts that may be end users or contact Axya Medical to contact any end users.

This recall is being made with the knowledge of the U.S. Food & Drug Administration.

We apologize for the inconvenience this issue has caused and thank you in advance for your cooperation in this matter. If you have any questions please contact our Customer Service Department at 800-611-2992 ext 687 (fax # 978-232-9998).

Sincerely,

  
President

Consignee:  
RISK MANAGEMENT / REGULATORY  
Address  
Address  
Address



Please complete the questionnaire and return it utilizing the envelope provided or by fax to 978-232-9998.

If you are returning product, please call our Customer Service Department at 800-611-2992 ext 687 for an RGA number.

1. Did your firm receive shipments of the Anchor Kits being recalled? Yes

No

(If NO, terminate questioning, sign the form and return using the envelope provided or by fax)

2. Do you have any of the affected product on hand? Yes

No

(If NO, terminate questioning, sign the form and return using the envelope provided)

3. If question 2 was answered YES, do you intend to return the product to Axya Medical Inc. as requested? Yes

No

4. If the answer to 3 is NO, please explain your intentions

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5. Have you received any reports of illness or injury related to this product? Yes

No

If you are returning product, please provide a listing of product in the space below (if more space is required attach a list):

Catalog #	Lot Number	Quantity Being Returned

Individual completing this form:

Signature

Date

Print Name