URGENT FIELD SAFETY NOTICE: MEDICAL DEVICE RECALL

13 Hole Scapula Medial Boarder Plate, Right
PL-SMB13R

Lot: 210139

Date:
Customer:
Address:

Acumed Reference Number: R11-005

Dear Customer,

This letter is to inform you that Acumed LLC is conducting a voluntary field safety corrective action of the 13 Hole Scapula Medial Boarder Plate, Right, part number PL-SMB13R, from the following lot 210139, because Acumed has determined that the plate was manufactured as an implant (PL-SMB13R), but was laser marked as a trial plate (PLT-SMB13R).

This product meets all Acumed implant specification, and there is no risk to the patient or end user.

Our records indicate that you received one or more devices from the affected lot. The product delivered to your facility is listed above and on the attached Field Action Reconciliation Form.

Please identify and segregate the affected product to prevent use of or exposure to.

This notice must be passed on to all who need to be aware within your organization or to any organization where the potentially affected product has been transferred.

We thank you to complete and return the enclosed response form to confirm you have received this notification. Include information relating to product that is not being returned.

Please contact your distributor, ORTHOAKTIV GMBH, for any replacement product.

The undersign confirms that this notice has been notified to the appropriate Regulatory Agency.

Thank you for your cooperation. We apologize for any inconvenience this may cause. If you have any questions regarding this issue, please contact your distributor, ORTHOAKTIV GMBH or Acumed's Quality Manager at +1 888-627-9957.

Kind Regards,

[redacted]
Acumed Quality Manager

Device Recall

Field Action Reconciliation Form

ORTHOAKTIV GMBH
AUGSBURGER STRASSE 9,
86157, AUGSBURG, DE
Tel. 821228190[redacted] Fax 82122819020
e-mail: [redacted]@orthoaktiv.de

Acumed Reference Number: R11-005

Product: 13 Hole Scapula Medial Boarder Plate, Right
Part Number: PL-SMB13R

Please complete the Field Action Reconciliation Form by following the steps listed below:

1. Verify listed product status (used or available for return).
2. If the product was used, indicate the quantity used in the "Quantity Used" column below, check the box below and complete this form, including the name of the hospital representative, and return to your distributor.
3. If the product is unused, indicate the quantity to be returned in the "Quantity Returned" column below, complete this form, including the name of the hospital representative, and return to your distributor. Verify the quantity being returned matches the quantity indicated below. Retrieve the product for return to your distributor.
4. After completion, make a copy of this form for the hospital records.
5. Fax the completed form to your distributor at 82122819020 .
6. Return the product and the original form to your distributor.

RA #:

Hospital:
Address: _____
_____
_____

Our records show that the following device(s) were sent to this site:

Part Number	Lot Number(s)	Quantity Sent	Qty. Used	Qty. Returned
PL-SMB13R	**210139**			

Check here if no devices remain at site.

Representative: _____ Date: _____
(Signature)

_____
(Printed Name)

Hospital Representative: _____

Site Phone Number: _____ Fax Number: _____