ACUMED®

Innovative Solutions

URGENT FIELD SAFETY NOTICE: MEDICAL DEVICE RECALL

Depth Gauge
FSCA-R12-005
Type of action: Removal

Date: 6 December 2012

Attention: [redacted]

Details on affected devices:
Depth gauge - 6-65mm, Acumed part number 80-0623, batch 251896.

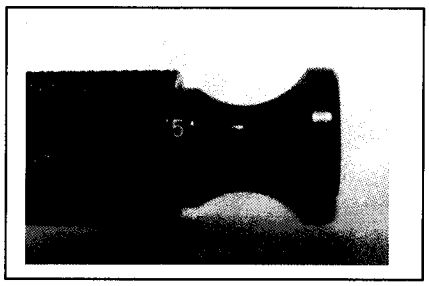
Description of the problem:
The depth gauge may incorrectly measure depth due to misplacement of a laser mark. This hazard may cause incorrect depth measurement, resulting in a screw to be shorter than desired. A too-short screw may not provide sufficient purchase of bone to achieve the desired surgical result, thereby causing risk to the patient.

Advise on action to be taken by the user:
Please take the following steps:

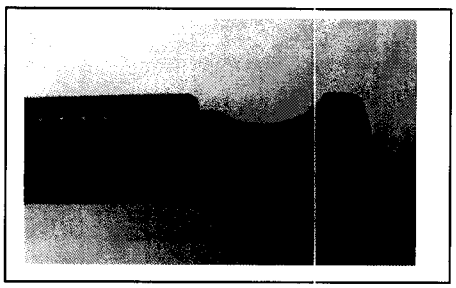
1. Identify product having batch number 251896.
    a. To locate the batch number, remove the plunger from the sleeve. The batch number is located to the left of the Acumed logo and to the right of the part number (80-0623).

2. For each depth gauge perform the following check:

    a. Fully engage the plunger with the sleeve by fully pushing the plunger into its sleeve).
    b. Visually inspect the portion of the plunger body that protrudes from the rear of the sleeve. Be sure to inspect the full circumference of the plunger (360°).
    c. If any portion of the plunger laser mark is visible beyond the edge of the sleeve, the depth gauge must be removed from service and quarantined - see photo below labeled "Incorrect Laser Marking".
    d. If no portion of the laser mark is visible beyond the edge of the sleeve, the depth gauge may be returned to service - see photo below labeled "Correct Laser Marking".



Incorrect Laser Marking



Correct Laser Marking

3. Return depth gauges with plunger laser mark visible beyond the edge of the sleeve to Acumed immediately.
    a. Contact Acumed International Business Services at +1 888-627-9957 to obtain a return authorization (RA) number and shipping address before returning any product. Clearly identify all returned product with this RA number.

ACUMED®

Innovative Solutions

Transmission of this Field Safety Notice:

This notice must be passed on to all within your organization who need to be aware and to any organization where the potentially affected devices have been transferred. Please notify other organizations on which this action has an impact.

Please maintain all documentation associated with this notice until March 27, 2013, to ensure effectiveness of the corrective action.

Contact reference person:

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

Please contact Acumed International Business Services +1 888-627-9957 to order replacement product.

The undersigned confirms that the appropriate Regulatory Agencies have been notified.

Thank you for your cooperation. We apologize for any inconvenience this may cause. If you any questions regarding this notice, please contact me at +1 888-627-9957.

Sincerely,

[redacted]
Quality and Regulatory Manager

ACUMED®

Innovative Solutions

*** IMPORTANT ***

Additional Information on Recall Requested to Distributors

Date:

Attention: Distributors

The Competent Authority (CA) in your country will probably require the following information in relation to this medical device recall:

1. Shipment dates
2. Quantities shipped
3. Name, address and phone number of hospital/user facilities who received the medical devices
4. Copies of recall letters sent to hospital/user facilities. (CA will require the proof that the recall has been effectively conducted)
5. Reconciliation between the quantities sent to hospitals/user facilities and the quantities returned to your distributorship
6. A statement that no incidents occurred.

We suggest you include the attached response sheet with your recall letter and/or fax to the hospital/user facility.

We wanted to give advance notice so that you can complete and maintain the recall documentation accordingly.

We appreciate your help facilitating this recall. Please feel free to contact us if we can be of further assistance.

ACUMED®

Innovative Solutions

DISTRIBUTOR RESPONSE FORM. DATE:

PLEASE COMPLETE THIS FORM AND RETURN WITHIN 7 DAYS

CUSTOMER:
Hospital/Institution name:
Address:
Phone:
Fax:
Contact name:

According to our records, we have shipped to you on behalf of Acumed LLC the following "DEVICE" (REF: _____ LOT:_____)

Please record the quantity returned in the table.
Please record a zero for no inventory found

Lot Number	Quantity shipped	Quantity returned

Have you received any reports of a malfunction with these devices ?

NO YES

Have you received any reports of injury to patient or user with these devices ?

NO YES

Hospital representative: _____ Date _____

A completed response form shall be faxed to the Attention of _____

on Fax Nr _____ or mailed to the following address:

"DISTRIBUTOR" address: