



URGENT: FIELD SAFETY NOTICE - MEDICAL DEVICE RECALL

Acumed 045" X 6" ST Guide Wire Part Number 45-0029-S Batch Number: 391681

Acumed 054" X 7" ST Guide Wire Part Number 45-0031-S Batch Number: 391680

FSCA: R17-001

Type of action: Removal

February 20, 2017

TO: Orthopaedic Surgeons, Risk Managers, and Healthcare Facilities

ISSUE: It has come to Acumed's attention that two batches of Guide Wires have been incorrectly packaged. For only the two batches listed below, the guide wires sized as .045" X 6" were packaged as .054" X 7" guide wires and those sized as .054" X 7" were packaged as .045" X 6" guide wires. There is a possibility that the using the incorrect guide wire size can cause health hazards, such as mal or nonunion, need for revision surgery, and histological response (if wire breaks).

To date, there have been no reported incidents of injury associated with this product. A voluntary recall to withdraw the following guide wires from the field has been issued for the batches listed in the table below.

Part Number	Description	Batch Number	UDI
45-0029-S	.045" X 6" ST Guide Wire	391681	20806378029384-391680160816230816
45-0031-S	.054" X 7" ST Guide Wire	391680	20806378029360-391681160816230816

Replacement guide wires will be shipped.

If you become aware of any adverse events, please report them immediately to your Acumed distributor at the address below or to Acumed Business Services via email at BusinessServices@acumed.net or via phone at +1 877 627-9957

RECOMMENDATION: If you have any of these product, **immediately stop using the product and quarantine it.**

Contact your distributor at the telephone number or email address below to receive further instruction for returning the products. A replacement set of plates will be shipped.

Complete the attached Device Recall Notification Reply Form and return it to:

Acumed National distributor representative: **Orthos Medical**

Address: **8 Sandford Office Park. Dublin IE 18. Republic of Ireland**

Contact : **Robert Nutty** .E-mail: robert@orthosmed.com Phone: 353 1 6602779

TRANSMISSION OF THIS FIELD SAFETY NOTICE: This notice needs to be passed on all those who need to be aware within your organization or to any organization where the recalled devices have been transferred.

We appreciate your immediate attention and cooperation and sincerely regret any inconvenience caused by this action.

Anthony M. Damas
Vice President of Quality, Regulatory, Compliance and Project Management
Acumed LLC
5885 NW Cornelius Pass Rd
Hillsboro, OR 97124 USA
503-627-9957



Attachment: Response form to be returned to your Acumed distributor within 7 days.

**RECALL: Acumed 045" X 6" ST Guide Wire Part Number 45-0029-S Batch Number: 391681
Acumed 054" X 7" ST Guide Wire Part Number 45-0031-S Batch Number: 391680**

FSCA: R17-001

PLEASE COMPLETE THIS RESPONSE FORM AND RETURN IT WITHIN 7 DAYS

DATE:

CUSTOMER:

Hospital/Institution name:

Address:

Phone:

Fax:

Contact name:

According to our records, we have shipped to you the following recalled devices (columns 1 and 2)
Please record the quantity to be returned in the column (4) of the table.
Please record a zero if no inventory was found.

1. Part Number	2. Batch Number	3. Quantity shipped	4. Quantity to be returned
45-0029-S	391681		
45-0031-S	391680		

Have you received any reports of a malfunction with these devices? Yes No

Have you received any reports of injury to patient or user with these devices? Yes No

Hospital/institution representative: _____ Date _____

Fax or e-mail this form to:

Acumed National distributor representative: **Orthos Medical**

Address: **8 Sandymount Office Park, Dublin IE 18, Republic of Ireland**

Contact : **Robert Nutty** .E-mail: robert@orthosmed.com Phone: 353 1 6602779