
Urgent Field Safety Notice

MEDICAL DEVICE RECALL

**AlgiNot FS Volume Recall
Due to Product Performance Issue**

24 February 2012

Customer Name/Address

Dear Valued Customer:

Details on affected devices:

The AlgiNot FS Volume lot number included in the scope of this notification is as follows:

Product	Part Number	Lot Number
AlgiNot FS Volume Intro Kit	34683	1-1017
AlgiNot FS Volume Volume Refills	34682	

Description of the problem:

As part of our internal quality standards, Kerr Hawe is voluntarily recalling the above lot of AlgiNot FS Volume, some of which was shipped to your office.

We are requesting return of the product you received from these lots because it has come to our attention that the affected product may set harder than expected, which could result in a material that may be more difficult to remove. While the product's hardness is below that of other VPS materials, use of it on patients with loose teeth may result in possible tooth fracture or tooth extraction. Please discontinue use of the product. The units involved were shipped between February and April 2011 and are listed below.

Advise on action to be taken by the user:

Please review the lot numbers listed above to determine if you have any of the affected products in your inventory. Kerr Hawe is requesting your cooperation in returning any affected product which you still have in stock. Product that is returned will be replaced at no charge.

KERR HAWE KINDLY REQUESTS YOUR COOPERATION IN COMPLETING AND FAXING BACK THE ENCLOSED RECALL REPLY FORM IN ORDER TO CONFIRM YOUR RECEIPT OF THIS RECALL. IT WOULD BE APPRECIATED IF YOU COMPLETE AND RETURN THE RECALL REPLY FORM,

REGARDLESS OF WHETHER YOU HAVE ANY PRODUCT IN YOUR INVENTORY TO CONFIRM YOUR RECEIPT OF THIS NOTIFICATION.

If you have any of the product listed above please contact KerrHawe Customer Care at 00800 41 05 05 00 to receive an RGA number. The RGA will allow for a quick return and credit note. As you are an authorized Kerr Hawe distributor, we request that you also identify and recover the affected product lots listed above that may have been shipped to your customers.

Transmission of this Recall Communication:

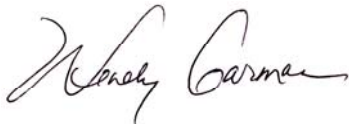
Kindly pass this notice on to all those within your organization who need to be aware of this Recall Communication. Additionally, please pass this notice to any organization where the affected AlgiNot FS Volume product may have been shipped.

We sincerely apologize for the inconvenience this causes you and your patients. Pentron continues to strive to be a leader in quality products and we have made prompt system improvements to eliminate a recurrence of this type of problem.

Your cooperation in this matter is greatly appreciated.

Thank you for your patience and support.

Sincerely,

A handwritten signature in black ink, appearing to read "Wendy Garman". The signature is fluid and cursive, with the first name "Wendy" being more prominent than the last name "Garman".

Wendy Garman
Director, Regulatory Affairs

Customer Name/Address

AlgiNot FS Volume Recall Return Form

Product	Part Number	Lot Number
AlgiNot FS Volume Intro Kit	34683	1-1017
AlgiNot FS Volume Volume Refills	34682	

- We acknowledge receipt of the AlgiNot FS Volume Recall Communication. We have checked our inventory and were able to locate one or more of the above-mentioned product. We will be returning the following quantity to Kerr Hawe.***

Part Number	Quantity being returned

If you have any of the product listed above please contact KerrHawe Customer Care at
00800 41 05 05 00 to receive an RGA number.

- We acknowledge receipt of the AlgiNot FS Volume Recall Communication. We have checked our inventory and were unable to locate any of the above-mentioned product.***

Contact Person (Please Print)

Facility

Signature

Date

**PLEASE FAX THIS ACKNOWLEDGEMENT FORM TO THE FOLLOWING NUMBER
REGARDLESS OF WHETHER YOU HAVE ANY PRODUCT TO RETURN.**

00800 41 05 05 14