

URGENT – Field Safety Notice

Article Number	Product Name	Batch Numbers
456402	4 Ganged Ultraport HF Stopcock	1370261401 1370266701 1370271701

Date
July 27, 2015

Dear Sir/Madam,

B. Braun Medical Ltd (Ireland) has received the enclosed Field Safety Notice from the supplier of the above product, B. Braun Medical Inc (USA), relating to a batch specific voluntary recall of the above mentioned product.

This product is distributed in Ireland via B. Braun Medical Ltd and our records show that you received the batches specified in the table above, which were distributed on the Irish market from 26th August 2013 to 21st March 2014.

Actions to be taken by the USER

We kindly ask you to initiate the following activities immediately and with priority:

- Immediately examine your stock to determine whether you have affected 4 Ganged Ultraport HF Stopcocks.
- Discontinue use of the product immediately.
- Quarantine all units in a secure, segregated area.
- Complete and sign the enclosed 'Recall Confirmation Form' and fax this back to us (fax no. 01-7091889) to confirm that you have received this notice and advise the quantity of affected product to be returned.

*Please return the completed form by **Friday 7th August 2015**, or sooner if possible.*

A member of B. Braun Medical Ltd will then be in touch with you to organise collection of any quarantined units. Please enclose the Batch Recall Confirmation Form with this collection.

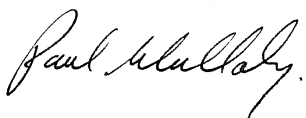
Credit will be provided for any affected product returned. A new order should be placed for any replacement product you may require.

If more information is needed, please contact:

Robert Bannon
OEM Sales Consultant,
Telephone: 086 8339836
Email: robert.bannon@bbraun.com

We appreciate your immediate attention and apologise for any inconvenience caused.

Yours sincerely,



Paul Mullaly
Managing Director



Roberta Egan
Regulatory Affairs Manager

July 27, 2015

BATCH RECALL CONFIRMATION FORM

4 Ganged Ultraport HF Stopcock

Please complete this form, even if you do not have any of the concerned product and fax this form back to Fax No. 01-7091889

- 1. We hereby confirm that we are aware of the Field Safety Notice from 27th July 2015 concerning the 4 Ganged Ultraport HF Stopcock. The Field Safety Notice was communicated within our organisation.**
- 2. Please mark accordingly:**

We do not have any of the affected product in stock.

or

We will return the following products:

Article Number	Device Name	Batch Number	Quantity to be Returned
456402	4 Ganged Ultraport HF Stopcock	1370261401	
		1370266701	
		1370271701	

Organisation:	
Address:	
Contact Name:	
Contact Phone Number:	
Contact e-mail address:	
Date and signature	



B. Braun Medical Inc.

901 Marcon Blvd.
Allentown, PA 18109
Telephone: (800) 227-2862
Fax: (610) 849-1197
E-mail: PA_QualityAssurance.BBMUS_Service@bbraun.com

July 22, 2015

**ELCAM MEDICAL ISSUED
URGENT MEDICAL DEVICE RECALL NOTIFICATION**

Dear Valued Customer:

Elcam Medical, manufacturer of the stopcocks and manifold products identified below, has notified B. Braun Medical Inc. of an Urgent Medical Device Recall for the potential of blisters to be punctured. This issue was identified by Elcam Medical during their manufacturing packaging process. Elcam Medical indicates that the use of punctured blisters may lead to a potential risk of contamination.

Our records indicate that you are in receipt of affected product and further use should be discontinued immediately. Please review the below necessary information and actions required.

Catalog Number	Description
456060	DISCOFIX HIGH-FLOW STOPCOCK
456201	2 GANGED HF LARGEBORE STOPCOCK
456202	2 GANGED ULTRAPORT HF STOPCOCK
456301	3 GANGED HF LARGEBORE STOPCOCK
456302	3 GANGED ULTRAPORT HF STOPCOCK
456401	4 GANGED HF LARGEBORE STOPCOCK
456402	4 GANGED ULTRAPORT HF STOPCOCK
456501	ULTRAPORT 4-WAY STOPCOCK W/ SINGLE VALVE
456502	ULTRAPORT 4-WAY STOPCOCK W/ DUAL VALVE
457202	ULTRAPORT ZERO 2 GANG MANIFOLD
457302	ULTRAPORT ZERO 3 GANG MANIFOLD
457402	ULTRAPORT ZERO 4 GANG MANIFOLD
457501	ULTRAPORT ZERO SINGLE PORT STOPCOCK
457502	ULTRAPORT ZERO DUAL PORT STOPCOCK

*Note: Refer to the Elcam Recall Notification for a list of the impacted lots and distribution dates for each item.

Actions Required By B. Braun Medical Customer/User:

1. Review the Product Recall Notification in its entirety and ensure that all users in your organization of the above mentioned product, and other concerned persons, are informed about this voluntary product recall. If you are a distributor, please forward this recall notification to your customers.
2. Determine your current inventory of the affected lots within your facility. Do not destroy any affected product.
3. Utilizing the attached "Product Removal Acknowledgement," form, record the total number of individual units (within partial cases) and the number of full-unopened cases. If you have no inventory remaining, please enter zero (0) on the form.

4. Return the completed "Product Removal Acknowledgement" form to B. Braun Medical Inc. Quality Assurance department by faxing the form to (610) 849-1197 or e-mail to PA_QualityAssurance.BBMUS_Service@bbraun.com within two (2) weeks of receipt, even if the total inventory in your possession is zero (0). It is important this form is returned, so BBMI can meet its United States Food and Drug Administration regulatory requirement.
5. If you have any full cases, partial cases or unused individual pieces of these affected products, please call B. Braun Medical Inc. Customer Support Department at (800) 227-2862 to arrange for return and replacement product. A B. Braun Medical Inc. Customer Support Representative will provide you with instructions for handling the affected product. We will arrange for all affected product to be returned to B. Braun Medical Inc. for proper disposition.

B. Braun is committed to continuously improving the safety and effectiveness of our products. We apologize for any inconvenience this may cause. Should you have any questions or concerns regarding the attached information, please contact our Customer Support Department at (800) 227-2862. French speaking customers may call (800) 624-2920.

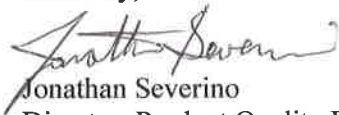
For U.S. Customers:

Adverse reactions with the identified Stopcocks should be reported to B. Braun at (800) 227-2862. Any adverse reactions experienced with the use of this product should also be reported to the FDA's MedWatch Program by phone at 1-800-FDA-1088, by Fax at 1-800-FDA-0178, by mail at MedWatch, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787, or on the MedWatch website at: <https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm>

For Canadian Customers:

Adverse reactions with the identified Stopcocks should be reported to B. Braun at (800) 627-7867. French speaking customers may call (800) 624-2920. Any adverse reactions experienced with the use of this product may also be reported to the Health Products and Food Branch Inspectorate at: http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/md_prob_rep-rap_incident_im-eng.php

Sincerely,



Jonathan Severino
Director, Product Quality Excellence
B. Braun Medical Inc.

Enclosures