

[Insert CUSTOMER NAME]  
ATTN: RISK MANAGER  
[Insert CUSTOMER ADDRESS]

[Insert Date]

via Federal Express

**URGENT MEDICAL DEVICE RECALL (Removal)  
IMMEDIATE ACTION REQUIRED**

**ACROBAT V Vacuum Off-Pump System and ACROBAT SUV Vacuum Off-Pump System  
AXIUS XPOSE 3 Access Device and XPOSE 4 Access Device  
Product manufactured from September 5, 2012 – June 19, 2014**

<b>Customer Number</b>	<b>Institution Name</b>
<i>customize</i>	<i>customize</i>

Dear Risk Manager,

This notification is to inform you of an urgent voluntary recall of the following:

Product Name	Product Code/REF Number
ACROBAT V Vacuum Off-Pump System	OM-9100S
ACROBAT SUV Vacuum Off-Pump System	OM-9000S
AXIUS XPOSE 3 Access Device	XP-3000
XPOSE 4 Access Device	XP-4000

An internal finding identified the presence of pinholes/cuts in some of the tyvek pouches of the vacuum tubing sets included as an accessory to these products. As a result, there is a potential for the pouch integrity to be compromised, which may result in compromised sterility of the product. If the compromised product is used in surgery there is a potential risk of infection for the patient.

A review of our records indicates that you have received one or more of the units affected by this recall. Consistent with this voluntary recall; we are requiring the return of all of the products as listed in **Attachment 1** in this notification.

**Please examine your inventory immediately to determine if you have any of the products listed. If so, please remove the affected products and place in a secure location.**

This voluntary recall only affects the products listed; no other products are affected by this voluntary recall.

**You must acknowledge receipt of this notification by completing and faxing back the attached Field Action Response form, whether or not you have any affected products.**

Note: If you have acted as a **distributor** for any product from the lots listed, please immediately contact those accounts, advise them of the recall situation, and have them return any affected stock to you. Then complete the Field Action Response form attached.

We appreciate your understanding and thank you for your continued support. We apologize for any inconvenience or concern this may have caused.

If you have any questions, please contact your local MAQUET Medical Systems sales representative or our Customer Service at +1 408-635-0700.

Thank you for your cooperation and immediate assistance.

Sincerely,



Marylou Insinga  
Specialist II, Regulatory Affairs and Field Action Compliance  
MAQUET  
45 Barbour Pond Drive  
Wayne, New Jersey 07470  
Email: [Marylou.insinga@maquet.com](mailto:Marylou.insinga@maquet.com)

## Attachment 1 Product List

OM-9100S	OM-9000S	OM-9000S Cont'd	XP-3000	XP-4000	XP-4000 Cont'd
25081363	25083285	25096305	25061930	25061406	25085516
25081832	25083405	25096404	25062239	25061961	25085696
25083629	25083504	25096913	25063171	25062341	25086333
25084722	25083904	25097097	25063264	25062853	25086530
25086515	25084006	25097336	25064005	25063026	25087192
25087723	25084498	25097417	25064805	25063351	25088336
25089063	25084648	25097747	25065216	25063594	25088517
25089942	25084928	25097801	25066072	25064160	25089557
25090685	25085094	25098540	25066261	25064428	25089623
25091907	25085850	25098968	25067242	25064917	25090324
25092783	25086057	<b>End of list</b>	25067493	25065315	25090692
25092968	25086330		25067915	25065547	25091410
25093960	25086468		25068869	25067036	25091811
25095207	25086786		25070671	25067396	25092398
25096649	25086869		25071619	25068245	25092567
25097068	25087249		25072468	25068555	25093083
25097679	25087330		25073684	25069189	25093570
25097895	25087412		25075060	25069589	25094620
25098213	25087793		25077055	25069971	25094845
<b>End of list</b>	25088394		25077999	25070492	25095211
	25088704		25078510	25070808	25095862
	25089154		25078808	25071242	25097087
	25089224		25080773	25072056	25097274
	25089724		25081495	25072852	<b>End of list</b>
	25090578		25082997	25073562	
	25090748		25084179	25074441	
	25090943		25086061	25075249	
	25091171		25087498	25075644	
	25092128		25088896	25076681	
	25092272		25090502	25077208	
	25092690		25090832	25077638	
	25092813		25091779	25078154	
	25093167		25092248	25079334	
	25093281		25092884	25079975	
	25094024		25093619	25080256	
	25094065		25094030	25080465	
	25094473		25095768	25081324	
	25094712		25096118	25081566	
	25094860		25096687	25081959	
	25095107		25097508	25083287	
	25095600		25098402	25083699	
	25095769		25098904	25084533	
	25096128		<b>End of list</b>	25085038	