

June 24, 2010

via email

URGENT DEVICE REMOVAL IMMEDIATE ACTION REQUIRED

Dear Valued Customer.

This notification is to inform you of an urgent voluntary recall of select lots of the HEARTSTRING Aortic Cutter 4.3 MM (AC-3043). As a result of routine production quality monitoring, it was brought to our attention that the pouch seal integrity for these products may not be adequate. An investigation revealed irregularities in the seal on the pouch potentially occurring due to manufacturing related causes. Although the likelihood of occurrence is low, there is a potential for seal integrity to be compromised, which may result in compromised sterility of the product. If such a product is used in surgery it may result in an increased chance of infection for the patient.

Based on our records, your hospital has recently purchased products that may have been affected. Consistent with this voluntary recall, we are requiring the return of all of the following products:

Product Name	Part Number	Affected Lots
HEARTSTRING Aortic Cutter 4.3 MM	AC-3043	9081071

Please examine your stocks immediately to determine if you have any product from the lots listed above on hand. If so, please discontinue dispensing (distributing) the lot and complete the Field Action Response form attached.

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.

Please note that 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.

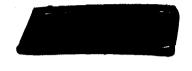
For your convenience, all affected products that are returned may be exchanged with other unaffected HEARTSTRING Aortic Cutter 4.3 MM devices. Please contact your local MAQUET Cardiovascular sales representative or Customer Service at +1-408-635-0653 or Intl.cscustserv@maquet.com for the exchange.

We appreciate your understanding and thank you for your continued support as we strive to provide you up-to-date information on the quality of our products. We apologize for any inconvenience or concern this Field Action may have caused you.



MAQUET Cardiovascular is committed to providing safe and high quality products. If you have any additional questions, please contact your local MAQUET Cardiovascular sales representative or our Customer Service at +1-408-635-0653 or Intl.cscustserv@maquet.com.

Sincerely,



Director, Regulatory Affairs

MAQUET CARDIOVASCULAR 170 Baytech Drive San Jose, CA 95134 Phone: 408.635.3900 Fax: 408.635.3901 www.maquet.com



FAX BACK TO +1- 408-635-0701

Field Action Response Form Product Handling Instructions for Accounts					
RE: INADEQUATE SEAL INTEGRITY IN SELECT LOTS OF HEARTSTRING AORTIC CUTTER 4.3 MM					
Institution Name:					
Step 1: Please list all remaining products	s with lot numbers and c	quantity remaining.			
Note: 1 Carton = 5 each of HEARTST Units within each Carton and record t			the number of		
Product Name	Part Number	Lot Number	Unit Quantity Remaining		
Example: Aortic Cutter 4.3 MM	Example: AC-3043	Example: 9081071	Example: 7		
Step 2: If you do not have any of the affe below, and skip to Step 4. I confirm that my institution does Cutter 4.3 MM in our possession	not have any of the affe	·			
Please initial:					
Step 3: Please contact MAQUET Cardio affected lots of the HEARTSTRII			if you have any		
A MAQUET Cardiovascular Cust authorization (RMA) number and	•				
RMA Number:	_				
Step 4: Please fill out the bottom of this of Cardiovascular Customer Service		empleted document to	MAQUET		
Hospital Representative: Signature:		Date:			
Print Name		Phone:			