MAQUET
GETINGE GROUP

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.

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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,

[redacted]
Director, Regulatory Affairs

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MEMBER OF THE GETINGE GROUP

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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

Customer Number:
Institution Name:

Step 1: Please list all remaining products with lot numbers and quantity remaining.

Note: 1 Carton = 5 each of HEARTSTRING AORTIC CUTTER Units. Please count the number of Units within each Carton and record the total quantity of Units remaining.

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 affected products in your possession, please initial the statement below, and skip to Step 4.

I confirm that my institution does not have any of the affected lots of the HEARTSTRING Aortic Cutter 4.3 MM in our possession.

Please initial: _____.

Step 3: Please contact MAQUET Cardiovascular Customer Service at 1-408-635-0653 if you have any affected lots of the *HEARTSTRING Aortic Cutter 4.3 MM.*

A MAQUET Cardiovascular Customer Service representative will issue a return material authorization (RMA) number and provide shipping instructions. Please note your RMA number.

RMA Number: _____

Step 4: Please fill out the bottom of this document and fax the completed document to MAQUET Cardiovascular Customer Service at +1-408-635-0701.

Hospital Representative: Signature: _____ Date: _____

Print Name: _____ Phone: _____