

URGENT NOTICE

PRODUCT RETURN MYXO ETLOGIX ANNULOPLASTY RING Model 5100, All Sizes, All Lots

December 5, 2008

Attention: Risk Management

cc: Department of Cardlac Surgery

Re:

Myxo ETlogix Annuloplasty Ring, Model #'s 5100M26, 5100M28, 5100M30, 5100M32, 5100M34,

5100M36, 5100M38, and 5100M40, Sizes 26mm - 40mm

Dear Valued Customer.

This request to return all Myxo rings to Edwards has been initiated because the FDA questioned the appropriateness of the product's name and disagreed with the company's conclusion that a 510(k) premarket notification was unnecessary prior to distributing the product. These decisions were not prompted by any product performance issues, but instead reflect the company's commitment to being responsive to the FDA. As a result, Edwards is changing the name of the device and has submitted a 510(k) application to the FDA, which is currently under review.

Should you receive questions about the Myxo ring from patients, please inform them that these decisions were not prompted by product performance issues. If you or any of your patients would like to speak with an Edwards representative, the company would be pleased to make available a member of our medical staff.

All Myxo model sizes (26mm through 40mm) are being collected. The affected product codes are 5100M26, 5100M28, 5100M30, 5100M32, 5100M34, 5100M36, 5100M38, and 5100M40.

Please check your inventory for any affected product and return all unused product from your stock to Edwards. Please call **Edwards Customer Service** at **888.570.4012** (6:00 AM PDT to 4:30 PM PDT) to arrange for return of any unused product and obtain information about replacement product.

Please return all unused product to:

Edwards Lifesciences LLC Attn: Returned Goods 1212 Alton Parkway Irvine, CA 92614

After you have verified your inventory, please complete the attached Confirmation Form. Please complete and return this form even if you do not have any affected units at your facility. This will allow us to verify the completion of this initiative.

Please return the Confirmation Form by FAX to: 800.422.9329, Attention: Myxo Return Coordinator.

We sincerely regret the inconvenience caused by this action and greatly appreciate your immediate attention to this matter.

Sincerely,

Donald E. Bobo, Jr.

Corporate Vice President, Heart Valve Therapy



Myxo ETIogix Annuloplasty Ring Return Response

Check if no MYX	
Cino	
Size	Number of units to be returned
26mm	
28mm	
30mm	
32mm	
34mm	
36mm	
38mm	
40mm	
	28mm 30mm 32mm 34mm 36mm 38mm

Please call 888-570-4012 to request an RGA number and if you have any questions.

Please fill in the number of units being returned and the RGA number and Fax completed form to the Return Coordinator at 800-422-9329

Note: Please enter a zero "0" or indicate "none" if you have no inventory to return.



URGENT NOTICE

PRODUCT RETURN IMR ETLOGIX ANNULOPLASTY RING Model 4100, All Sizes, All Lots

December 8, 2008

Attention: Risk Management

cc: Department of Cardiac Surgery

Re:

IMR ETIOgix Annuloplasty Ring, Model #'s 4100M24, 4100M26, 4100M28, 4100M30, 4100M32, and

4100M34, Sizes 24mm - 34mm

Dear Valued Customer,

This request to return all IMR rings to Edwards was voluntarily initiated by the company as a result of its internal review of all Justification to File letters for its annuloplasty rings. In this context, Edwards decided to submit a new 510(k) application to the FDA for the IMR ring, and this submission is currently under review. The decision to submit a 510(k) for the IMR ring was not prompted by any product performance issues, but instead reflects the company's commitment to be responsive to the FDA.

Should you receive questions about the IMR ETlogix ring from patients, please inform them that these decisions were not prompted by product performance issues. If you or any of your patients would like to speak with an Edwards representative, the company would be pleased to make available a member of our medical staff.

All IMR ETlogix model sizes (24mm through 34mm) are being collected. The affected product codes are 4100M24, 4100M26, 4100M28, 4100M30, 4100M32, and 4100M34.

Please check your inventory for any affected product and return all unused product from your stock to Edwards. Please call **Edwards Customer Service** at **888.570.4012** (6:00 AM PDT to 4:30 PM PDT) to arrange for return of any unused product and obtain information about replacement product.

Please return all unused product to:

Edwards Lifesciences LLC Attn: Returned Goods 1212 Alton Parkway Irvine, CA 92614

After you have verified your inventory, please complete the attached Confirmation Form. Please complete and return this form even if you do not have any affected units at your facility. This will allow us to verify the completion of this initiative.

Please return the Confirmation Form by FAX to: 800.422.9329, Attention: IMR ETlogix Return Coordinator.

We sincerely regret the inconvenience caused by this action and greatly appreciate your immediate attention to this matter.

Sincerely,

Donald E. Bobo, Jr.

Corporate Vice President, Heart Valve Therapy



IMR ETIogix Annuloplasty Ring Return Response

In order to facilitate the RGA process, please record Serial Numbers prior to contacting Edwards.

IMR ETLOGIX RING Product Code List Serial Numbers to be returned (or enter "0" or "None" if no stock on hand) 4100M24 4100M26 4100M30 4100M32 4100M34

Customer/Hospital Name _	
RGA No.	
Print Name	(person completing this form)
Signature	Date

Please call 888-570-4012 to request an RGA number and if you have any questions.

Please fill in the serial number(s) of units being returned and the RGA number and Fax completed form to the Return Coordinator at 800-422-9329.

Note: Please enter a zero "0" or indicate "None" if you have no inventory to return.