ETHICON, INC.
a Johnson & Johnson company

P.O. BOX 151
SOMERVILLE, NEW JERSEY 08876-0151

Urgent Field Safety Corrective Action
May 11, 2015

Pressure Regulator (code: 1938)

Please distribute this information to appropriate personnel at your facility.

Dear Valued Customers,

Ethicon Inc. is contacting all customers who have Omrix Pressure Regulator(s) on hand, to inform them of Ethicon's ongoing efforts to minimize the risk of air or gas embolism related to spraying fibrin sealant products.

In August 2012, Ethicon and Omrix Biopharmaceuticals had sent out a communication to make you aware of the risk of fatal adverse events associated with improper spray application technique(s) of EVICEL® Fibrin Sealant (Human). We have received reports of air or gas embolism occurring in association with the use of spray devices employing a pressure regulator at higher then recommended pressures and closer than recommended distances (distance of device tips to the tissue surface) when administering EVICEL®.

Ethicon Inc. is initiating a Field Safety Corrective Action by removing all Omrix Pressure Regulators to ensure our products are used in a safe and effective manner. Users can continue to use our Evicel® Fibrin Sealant (Human) using the application device by dripping.

To date, there have been no air or gas embolism adverse events reported when the spray application technique is used according to the pressure and distance recommendations stated in the product Instructions for Use (IFU).

PRODUCT AFFECTED

All lots of Pressure Regulator (code: 1938)

ACTIONS REQUIRED FROM YOU

We need your help in ensuring that all affected product is located, accounted for and returned.

1. Examine your inventory immediately to determine if you have affected product on hand and **remove** the affected product(s).

2. Fill out the Customer Acknowledgement Form and pass it to your Ethicon sales representative or fax it to 6720 0750 **within 2 business days, even if you do not have affected product.** If you have product to be returned, keep a copy of this form for your records.

3. To return affected product, contact your Ethicon sales representative or contact our customer service at 6827 6096. Attach a photocopy of the Customer Acknowledgement Form with the products.

4. Please pass on this notice to anyone in your facility that needs to be informed.

5. Any adverse reactions or quality problems experienced with the use of this product should be reported as a complaint to Johnson & Johnson Medical Singapore following the usual procedure.

We apologize for any inconvenience this matter may cause. If you have any further questions, please call or contact the Ethicon sales representative.

Thank you for your cooperation and immediate assistance.

Yours sincerely,

[redacted]

Christiana Bielinski
VP, Biosurgery Quality and
Global Surgery Network Optimization
Ethicon Biosurgery

[redacted]

Richard Kocharian MD, PhD
Medical Director
Ethicon Biosurgery