ETHICON

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13th March 2015

Urgent FIELD SAFETY NOTICE

Omrix Pressure Regulator

Field Safety Corrective Action

Dear Health Care Professionals [Materials Managers, Operating Room Directors, Risk Managers and/or Surgeons],

We are contacting all customers who may have an Omrix Pressure Regulator to inform you of our ongoing efforts to minimize the risk of air or gas embolism related to spraying fibrin sealant products (previous notification sent May 2013).

In accordance with established recommendations issued by the European Medicines Agency in November of 2012, we are initiating the second phase of a Field Safety Corrective Action. This phase will include replacement of all Omrix Pressure Regulators with new units that cap the upper sprayable limit at 1.7 bar to further ensure our products are used in accordance to the manufacturer's recommendations.

As such, we will be replacing any Omrix Pressure Regulators with new units, capped at 1.7 bar.

In order to provide you with replacement CO_2 Pressure Regulators, we ask that you take the following actions below. Please note your local Ethicon Sales Representative may assist you in this process:

1. Examine your inventory to determine if you have Omrix Pressure Regulator device(s). Complete the enclosed Inventory Form and return it to your Local Ethicon Sales Representative, even if you do not have inventory of a pressure regulator.
2. If you are confirming the presence of one or more pressure regulators at your facility, please keep a copy of the completed Inventory Form.
3. Your local Ethicon Sales Representative will visit you to remove any current pressure regulators, replace the inventory with new units and conduct training to reinforce the information in this Field Safety Notice.

You may continue to use the existing Omrix Pressure Regulator until a replacement has been received. This notice should be passed on all those who need to be aware within your organization or where potentially affected devices may have been transferred.

We are available to answer any questions that you have, therefore please contact your local Ethicon Sales Representative or email mir_gsgs_emea@its.jnj.com to submit a Medical Information Request.

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The appropriate regulatory authorities have been notified of this FSCA and notice.

Thank you for your prompt attention to this matter.

Sincerely,

Christiana Bielinski
Group Director, Quality & Compliance
Ethicon Biosurgery

Richard Kocharian, M.D., Ph.D.
Medical Director,
Ethicon Biosurgery