



March 17, 2016

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 an update to the Instructions for Use (IFU).

In an effort to enhance consistency between the labeling of the Omrix Pressure Regulator and the Omrix Evicel Solutions for Sealant, we have updated the IFU for the Pressure Regulator to remove the statement as indicated below:

- ~~Spray application of EVICEL™ should not be used in endoscopic procedures where the minimum recommended distance of 4 cm cannot be maintained. For laparoscopic procedures using accessory tips, see the recommendations in Table 2~~
- When applying EVICEL™ in open procedures, be sure to use a pressure and a distance from the tissue within the ranges recommended by the manufacturer.
- For laparoscopic procedures using accessory tips, see the recommendations in Table 2.

Spray parameters and risk information, as is currently labeled on the Pressure Regulator itself and in the Evicel Solutions for Sealant SmPC, remains unchanged.

You may continue to use the existing Omrix Pressure Regulator. This labeling update does not reflect any change in safety, efficacy or procedure to use the device.

Enclosed with this letter is a copy of the updated IFU. We ask that you please replace the existing IFU that was originally supplied with any Omrix Pressure Regulators at your facility with this updated IFU immediately. Your local Ethicon representative will be in contact shortly, in order to arrange an onsite visit to ensure the IFU has been replaced and document the completion of the replacement with you directly.

This notice should be passed on to 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. To speak with someone at the company, please contact your sales representative.

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

Thank you for your prompt attention to this matter.



Sincerely,

