ETHICON™ | Biosurgery

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Urgent Product Information
EVICEL® Solutions for Sealant
All Lots and Product Codes

07th March 2013

Risk of life-threatening air or gas embolism with the use of a spray device administering Evicel product.

Dear Healthcare Professional, **Omrix Biopharmaceuticals NV would like to inform you of important information on the safety of spray application of Evicel®.**

Summary

- Five life-threatening cases of air or gas embolism have been reported worldwide since 2008 with the use of spray devices employing pressure regulators to administer Evicel®
- Such events appear to be related to the use of the spray device at higher than the recommended pressures, and/or in close proximity to the tissue surface.

The following instructions should be followed when using a spray device for Evicel® application to prevent air/gas embolism:

- Evicel should be sprayed using pressurised CO_2 gas only.
- Spray application of Evicel® should not be used in endoscopic procedures.
- In open surgery: when applying sprayable Evicel® using a pressure regulator device, the maximum pressure should be 1.7 bar [25 psi]. The product should be sprayed at a distance of at least 10cm from the tissue surface.
- In laparoscopic surgery: Evicel® spray application should only be used if it possible to accurately judge the spray distance as recommended by the manufacturer. The maximum pressure should be 1.4 bar [20 psi] and the product should be sprayed at a distance of at least 4cm from the tissue surface.
- Prior to applying EVICEL® the surface area of the wound should to be dried using standard techniques (e.g. intermittent application of compresses, swabs, use of suction devices).
- Blood pressure, pulse rate, oxygen saturation and end tidal CO_2 should be monitored closely when spraying EVICEL®, because of the possibility of occurrence of air or gas embolism.

The content of this letter has been approved by the European Medicines Agency (EMA) and the Medicines and Healthcare products Regulatory Agency (MHRA)]

Additional information on cases of air embolism

Five cases of air embolism (of which two had a fatal outcome) have been reported worldwide since 2008 in association with Evicel administered by spray application using a gas pressure regulator device. In all cases the spray device was used at higher than recommended pressures and/or in close proximity to the tissue surface.

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This letter follows the completion of the European Medicines Agency's recent review of the benefits and risks of fibrin sealants authorised for use by spray application using a gas pressure regulator device. The instructions summarised above will be included in the Summary of Product Characteristics (SPC) and the Patient Information leaflet (PIL) for the fibrin sealant (see Annex), in the Instructions for Use accompanying the devices used for spray application, and in the educational material.

Call for reporting

Please report any suspected adverse reactions to any medicine to the MHRA. Please report any suspected adverse reactions to any medicine or vaccine to the MHRA via the Yellow Card Scheme. The easiest way to report is online at http://www.mhra.gov.uk/yellowcard.

Alternatively, complete a paper Yellow Card form which you can post to "FREEPOST YELLOW CARD". Yellow cards can be found in the BNF, MIMS or ordered by calling the Yellow Card Information Service Free phone line on 0800 731 6789.

Any suspected adverse reactions of gas embolism observed during use of Evicel may also be reported to Omrix Biopharmaceuticals NV through your Ethicon Biosurgery Sales Representative.

To speak with someone at the company, please contact your sales representative, or call 0033 1 5500 2065 to speak with a member of our Medical Affairs department.

The MHRA has been advised of these occurrences.

Thank you for your prompt attention to this matter.

Sincerely,

Christiana Bielinski
Group Director, Quality and Compliance
ETHICON™ Biosurgery

Jeffrey Hammond MD, MPH, FACS
Group Director, Medical Affairs
Ethicon