Baxter

January 2013

Risk of air or gas embolism with the inappropriate use (too high pressure, too short distance) of spray devices administering fibrin sealant products: Tisseel Lyo, Tisseel Ready to use, and Artiss Solutions for Sealant

Dear Healthcare Professional,

Baxter Healthcare would like to inform you of important information on the safety of spray application of Tisseel Lyo, Tisseel Ready to use, and Artiss Solutions for Sealant

Summary:

- One possible case of a potential air embolism has been reported in association with Tisseel; however the causal association between the spray application of Tisseel and the onset of air embolism could not be established from this case.

- A total of 9 cases of air embolism have been reported in association with other fibrin sealants administered by spray application using a gas pressure regulator device. Of which three had a fatal outcome (in one case ultimately no product was administered). Such events appear to be related to the use of the spray device at a higher than recommended pressure, and/or in close proximity to the tissue surface.

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

For Tisseel and Artiss

- **In open-wound surgery: when applying sprayable fibrin solutions for sealant using a pressure regulator device, the maximum pressure should be 2.0 bar (28.5 psi). The product should be sprayed at a distance at least 10 cm from the tissue surface.**
- **Prior to applying sprayable fibrin solutions for sealant, the surface area of the wound should only be dried using standard techniques (eg, 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 fibrin solutions for sealant using a pressure regulator device, because of the possibility of occurrence of air or gas embolism.**

For Tisseel only

- **In laparoscopic procedures: when applying the product as a spray using a pressure regulator device, the maximum pressure should be 1.5 bar (22 psi). The product should be sprayed at a distance at least 2cm (recommended range 2-5cm) from the tissue surface.**

For Artiss only

- **Artiss is recommended for subcutaneous use only. Artiss is not recommended for laparoscopic use.**

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The content of this letter has been approved by the European Medicines Agency (EMA) and the Irish Medicines Board (IMB)

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 summarized 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.

Please distribute this information to all end-users of the concerned products.

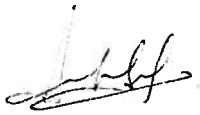
Call for Reporting

Please report any suspected adverse reactions to any medicine to the Irish Medicines Board using a Yellow Card obtained either from the Irish Medicines Board., or electronically via the website at www.imb.ie

Any suspected adverse reactions of gas embolism observed during use of Tisseel Lyo, Tisseel Ready to use and Artiss may also be reported to Baxter Healthcare directly by calling 01-206-5500, or by email on qa_dublin@baxter.com.

Should you have any questions or require additional information on the use of Tisseel, Tisseel Lyo, or Artiss, please contact Baxter Medical Information on +44 01635 206345 or by email at surecall@baxter.com.

Yours sincerely,



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Annex: Revised wording for fibrin sealant Summary of Product Characteristics (SPC) and Patient information Leaflet (PIL)

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