



January 2013

**Risk of air or gas embolism with the inappropriate use of spray devices administering fibrin sealant products: Tisseel Lyo, Tisseel Ready to use, and Artiss Solutions for Sealant**

Dear Healthcare Professional,

**Please read the following important information on the safety of spray application of Tisseel Lyo, Tisseel Ready to use, and Artiss Solutions for Sealant**

**Summary:**

- A total of 9 cases of air embolism (three were fatal and in one case ultimately no product was administered) have been reported in association with fibrin sealants (with the exception of Artiss) administered by spray application using a gas pressure regulator device. Such events appear to be related to the use of the spray device at a higher-than-recommended pressure, and/or in too-close proximity to the tissue surface.
- Out of these 9 cases there is just one that 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.

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

**For Tisseel and Artiss**

- **In open-wound surgery: when applying Tisseel or Artiss using a pressure regulator device, the maximum pressure should be 2.0 bar (28.5 psi). The product should be sprayed at least 10 cm or more from the tissue surface.**
- **Prior to applying Tisseel or Artiss, the surface area of the wound should only be dried using standard techniques (eg, intermittent application of compresses, swabs, use of suction devices).**
- **Closely monitor blood pressure, heart rate, oxygen saturation and end-tidal CO<sub>2</sub> when spraying Tisseel or Artiss, because of the possibility of air or gas embolism.**

### **For Tisseel only**

- **In laparoscopic procedures: when applying Tisseel as a spray using a pressure regulator device, the maximum pressure should be 1.5 bar (22 psi) and only CO<sub>2</sub> gas should be used. The product should be sprayed at least 2cm or more (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.**

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

**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 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 Tisseel Lyo, Tisseel Ready to use and Artiss may also be reported to Baxter Healthcare Pharmacovigilance on 01635 206360, or by email to [vigilanceuk@baxter.com](mailto:vigilanceuk@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 01635 206345 or by email at [surecall@baxter.com](mailto:surecall@baxter.com).

Yours sincerely,



**Dr Arunesh Sil**  
**Medical Advisor**  
MBBS, MS(ENT Surgery), DOHNS, MRCS.

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