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IMPORTANT SAFETY INFORMATION –CLASS LABELLING INFORMATION

11 October 2010

Dear Healthcare Professional

SUBJECT: Risk of Life-Threatening Air or Gas Embolism with the Use of Spray Devices Employing Pressure Regulator to Administer the products: Tisseel Kit

Baxter Healthcare Limited would like to notify you of an important safety update to the product information of the product Tisseel Kit.

Key Messages:

Air or gas embolism has occurred with the use of spray devices employing a pressure regulator to administer fibrin sealants. The event appears to be related to the use of the spray device at higher than recommended pressures and/or in close proximity to the tissue surface.

The safety update includes the following instructions for sealant application using a spray device

- **When applying Tisseel Kit using a spray device, the pressure should be within the range recommended by the spray device manufacturer**
- **In the absence of a specific recommendation from the spray device manufacturer, the pressure should not exceed 1.4-1.7 bars**
- **Tisseel Kit should not be sprayed at a distance closer than that recommended by the spray device manufacturer**
- **In the absence of a specific recommendation from the spray device manufacturer Tisseel Kit should not be sprayed closer than 10-15 cm from the tissue surface. This is also applicable when using the EasySpray device (for open surgery). When using the DuploSpray MIS spray device (for minimally invasive surgery) it should not be sprayed closer than 2cm**
- **When spraying Tisseel Kit, changes in blood pressure, pulse rate, oxygen saturation and end tidal CO_2 should be monitored because of the possibility of occurrence of air or gas embolism**
- **When using accessory tips with this product, the instructions for use of the tips should be followed**

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Additional information on cases of air embolism:

Several cases of air embolism have been reported with spray administration of other fibrin sealants using a pressure device. The following are examples of two cases of life-threatening (one fatal) air embolism received by other manufacturers of fibrin sealants: One 22 year-old patient died after administration of the product due to pressure use higher than the range recommended by the spray device manufacturer. The second case was as a result of the use of the spray within 1cm in a laparoscopic partial nephrectomy.

This communication has been agreed with the Irish Medicines Board.

Call for Reporting

Suspected adverse reactions should be reported 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.

Adverse reactions may also be reported to Baxter Healthcare directly by calling 01-206-5500 and asking for the Quality Department.

Should you have any questions or require additional information on the use of Tisseel Kit, please contact Baxter Medical Information on +44 1635 206345 or by email at surecall@baxter.com.

Yours sincerely,

Adrian Kilcoyne

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