

EMA advices on fibrin sealant spray applications

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Singapore: European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has recommended a number of new instructions for healthcare professionals using the fibrin sealants Tisseel, Tissucol, Artiss and Beriplast P (and associated names) to optimize the safe use of these medicines when applied as spray during surgery.

This follows the CHMP advice on two other fibrin sealants, Evicel and Quixil, adopted in November 2012. Fibrin sealants are used in a wide range of surgical procedures to help reduce local bleeding. They can be applied by dripping or spraying the solution onto bleeding tissue, where they form a fibrin clot, stopping bleeding and thereby helping the wound to heal.

The review of fibrin sealants was initiated following reports of gas embolism with Evicel and Quixil in association with the use of spray devices that use a pressure regulator to administer these medicines. These events appear to be related to the use of the spray device at higher-than-recommended pressures and/or in closer-than-recommended proximity to the tissue surface.

Although the risk of gas embolism with Tisseel, Tissucol and Artiss when applied as spray during surgery was considered to be very low, the committee concluded that the risk cannot be excluded, and recommended that the product information of these medicines be updated with new instructions to optimise their safe use.