

Air- or Gas-Pressurized Spray Devices: Risk of Air or Gas Embolism

U.S. Food & Drug Administration

AUDIENCE: Surgery, Operating Room Nursing

ISSUE: FDA has received reports of air or gas embolism occurring during or immediately after application of hemostatic drug or biological products using air- or gas-pressurized sprayers. These adverse events appear to be related to use of spray devices inconsistent with the approved product labeling and instructions for use. In some reports the device was used at higher than recommended pressure or at a distance too close to the surface of the bleeding site. Although rare, the reports describe air embolisms that are life threatening and include one fatality.

BACKGROUND: The manufacturers of all fibrin sealants licensed in the U.S. have updated the Warning and Precautions sections of the labels of EVICEL, Tisseel and ARTISS to emphasize the risk of air embolism and the need to use the recommended ranges of pressure and distance. The labeling of the spray devices and non-fibrin hemostatic drug or biological products also includes information on recommended pressures and distances.

RECOMMENDATIONS: Clinicians using air- or gas-pressurized spray devices for application of hemostatic drug or biological products should:

- Use the applicator, spray set, and pressure control device or regulator as recommended in the labeling or Information For Use of the hemostatic agent.
- Use an air or gas pressure setting within the range recommended by the manufacturer of the sprayer.
- Ensure that distance between the spray head and the tissue surface is not less than the minimum recommended by the manufacturer of the sprayer.
- Monitor blood pressure, pulse, oxygen saturation and end tidal CO₂ for signs of an air or gas embolism.
- Make sure the regulators are maintained properly and checked for safe performance regularly.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

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- Online: www.fda.gov/MedWatch/report.htm [1]
- Phone: 1-800-332-1088
- Mail: return the postage-paid FDA form 3500, which may be downloaded from the MedWatch "[Download Forms](#) [2]" page, to address on the pre-addressed form
- Fax: 1-800-FDA-0178

[07/09/2010 - [Safety Notification](#) [3] - FDA]

[10/05/2009 - [Important Drug Warning - Fibrin Sealants](#) [4] - FDA]

[10/2009 - [ARTISS \[Fibrin Sealant \(Human\)\] Prescribing Information](#) [5] - Baxter]

[11/2009 - [TISSEEL \[Fibrin Sealant\] Prescribing Information](#) [6] - Baxter]

[11/2009 - [EVICEL Fibrin Sealant \(Human\) Prescribing Information](#) [7] - Omrix]

[SOURCE](#) [8]

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<http://www.mdtmag.com/news/2010/07/air-or-gas-pressurized-spray-devices-risk-air-or-gas-embolism>

Links:

[1] <https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm>

[2] <http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm>

[3] <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm218523.htm>

[4] <http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/ucm209778.htm>

[5] <http://www.fda.gov/downloads/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/LicensedProductsBLAs/FractionatedPlasmaProducts/UCM073054.pdf>

[6] <http://www.fda.gov/downloads/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/LicensedProductsBLAs/FractionatedPlasmaProducts/UCM072968.pdf>

[7] <http://www.fda.gov/downloads/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/LicensedProductsBLAs/FractionatedPlasmaProducts/UCM114073.pdf>

[8] <http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm218530.htm>