

## News Release

**Contact:**

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### **Acacia, Inc. Announces Worldwide Voluntary Recall of IV Extension Sets with BD Q-Syte<sup>™</sup> Luer Access Device**

**Brea, CA (February 9, 2010)** – Acacia, Inc. (formally known as MPS Acacia) has voluntarily executed a product recall of certain lots of IV Extension Sets with BD Q-Syte<sup>™</sup> Luer Access Device. The BD Q-Syte<sup>™</sup> Luer Access Device is a Needleless Valve manufactured by BD (Becton, Dickinson and Company). Use of the affected BD Q-Syte<sup>™</sup> Luer Access Device may cause an air embolism or leakage of blood and/or therapy, which may result in serious injury or death. This field corrective action included notification to customers worldwide by letter.

The IV Extension Set with BD Q-Syte<sup>™</sup> Luer Access device is intended for use with other infusion therapy products in the administration of fluids into the intravenous system.

The following REF (catalog) and lot numbers, which were sold in the U.S., are included in the recall:

MPS Acacia IV Extension Set with BD Q-Syte **REF:**  
385150, 385151, 385164, 385165, 385166

**Lot Numbers:**

A1950, A1951, A1967, A1979, A2055, A2056, A2099, A2100, A2101, A2104

Patient safety and the quality and safety of our products are Acacia's first priorities. The recall was initiated on Dec. 18, 2009 after Acacia received information from BD of complaints received due to air entry through the bottom disk of the Q-Syte<sup>™</sup> septum. BD investigated and determined the root cause to be a manufacturing deviation. Though Acacia has not received any customer notification of product failures with the Acacia IV Extension Sets with BD Q-Syte<sup>™</sup>, product failures occurred with BD labeled devices that included BD Q-Syte<sup>™</sup> units distributed from November 2008 through November 2009.

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The root cause has been corrected by BD and preventive measures, including additional inspections and preventive maintenance of the line, have been implemented.

The approximately 217,000 IV Extension Sets with BD Q-Syte™ that were recalled were distributed in the United States exclusively to BD for distribution worldwide, which includes the United States, Canada, Europe, Asia, Australia, and North and South American Countries.

Acacia has notified the U.S. Food and Drug Administration and other worldwide health agencies, as necessary, and is working with them to coordinate recall activities. Clinicians or distributors with questions can contact Acacia at 1-800-486-6677 between 8:00 AM and 5:00 PM Pacific Standard Time, Monday-Friday, or dial directly at 714-257-0470.

Adverse reactions quality problems experienced with the use of this product may be reported to FDA's MedWatch Adverse Event Reporting program either on line, by regular mail or by fax:

- On line: [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm)
- Regular mail: Use postage-paid FDA form 3500 available at: [www.fda.gov/medwatch/getforms.htm](http://www.fda.gov/medwatch/getforms.htm). Mail to MedWatch 5600 Fishers Lane, Rockville, MD 20852-9787
- Fax: 1-800-FDA-0178

**About Acacia, Inc.**

Acacia, Inc., formerly known as MPS Acacia, founded in 1990, designs, develops and manufactures a comprehensive line of specialty I.V. therapy sets, specialty line extensions and accessories for infusion therapy, pain management tools, and pharmacy I.V. admix products for the hospital and home care markets.

Every Acacia product is firmly rooted in our core belief of constantly improving patient and caregiver safety. Our entire team prides itself on delivering only the highest quality medical products at manageable prices. For more information, please visit [www.acaciainc.com](http://www.acaciainc.com).

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