

Loma Vista Medical Reports That It is Ramping up Sales in U.S. and Europe of its FDA-Cleared and CE-Marked TRUE Dilatation™ Balloon Valvuloplasty Catheter Specifically Designed to Reduce ‘Rapid Pacing’ Time and Prevent Balloon Failure

The Associated Press

BURLINGAME, Calif.--(BUSINESS WIRE)--Feb 13, 2013--Loma Vista Medical announced today that it has established a direct sales force in the United States and has scaled its partnerships with seven (7) distributors in Europe in order to keep pace with the rapidly increasing demand for its FDA-cleared and CE-marked TRUE Dilatation™ Balloon Valvuloplasty Catheter.

The company also announced today that it has released updated versions of its product with enhanced features and an expanded size range.

“Standard blow-molded balloon technology has proven to be troublesome—if not inappropriate—for a range of clinical applications. It has shown significant clinical limitations in transcatheter valve procedures, including the risk of catastrophic failure and loss of embolic debris. Loma Vista Medical’s flexible composite technology has been specifically engineered to meet these challenges. With eight months of successful procedures behind us and zero structural failures, TRUE Balloons are quickly becoming the balloon of choice for transcatheter valve procedures. The Loma Vista product offers unmatched performance and superior reliability,” said Alex Tilson, founder and CEO of Loma Vista Medical.

Fabricated from tough, high-strength materials and designed to prevent the catastrophic failures seen with other heart valve dilatation balloons, the TRUE Dilatation Balloon is highly resistant to ruptures, punctures, and tears. Studies funded by the U.S. National Heart, Lung and Blood Institute (NHBLI) and others have reported failure rates of between 4% and 17% for conventional balloons used in BAV (balloon aortic valvuloplasty) and TAVI (transcatheter aortic valve implantation) procedures.

“Valves are measured precisely and are built precisely – TRUE Dilatation Balloons are share these same critical attributes,” Tilson said. Because the TRUE Dilatation Balloon is both precise and durable, it is designed to facilitate exact, restrained and dependable dilatations for BAV and TAVI procedures,” Tilson said. In addition, the Loma Vista Balloon can be inflated and deflated quickly for reduced ‘rapid pacing’ time, which may be important for treating elderly patients who are undergoing BAV and TAVI.

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“The U.S. and European markets are rapidly adopting our TRUE Dilatation Balloon platform because it represents a state-of-the-art paradigm for percutaneous heart valve prep and valvuloplasty. Clinicians have high demands for their BAV and TAVI balloons, and Loma Vista’s technology has proven uniquely able to meet those demands,” added Tilson.

About Loma Vista Medical

Headquartered in Silicon Valley (Burlingame, Calif.), Loma Vista Medical is a venture capital-funded medical device company that leverages a highly unique flexible composite technology platform to create the world’s most advanced medical balloons.

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