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Japan approves extended indication of CryoLife's BioGlue

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CryoLife Inc., a leading medical device and tissue processing company focused on cardiac and vascular surgery, announced that the Japanese Pharmaceuticals and Medical Device Agency (PMDA) has approved an expanded indication for BioGlue.

BioGlue is now indicated for adhesion and support of hemostasis for aortotomy closure sites, suture/anastomosis sites (including aortic dissection and anastomosis sites with a use of a prosthetic graft) and suture sites on the heart.

BioGlue was previously approved for aortic dissection procedures in Japan, which is estimated to be a $5 million market. The expanded indication potentially doubles the estimated BioGlue market opportunity in Japan to over $10 million.

CryoLife's marketing partner in Japan, Century Medical Inc. is expected to begin selling BioGlue in the third quarter of 2015 for the expanded indications. BioGlue is the leading surgical adhesive used in cardiovascular surgery around the world and is used in a wide range of reconstruction procedures.

To date, BioGlue has been used in over 1 million surgical procedures with more than 300 pre-clinical and clinical papers discussing its safety, efficacy, and application techniques.