

Informed Consent- Statement

All study participants, or their legal guardian provided informed written consent prior to study enrollment

* Correspondence to: Zhigang Li

Department of Thoracic Surgery, Shanghai Chest Hospital, affiliated with Shanghai Jiaotong University, 241 West Huaihai Road, Shanghai 200032, China;

Telephone: 0086 21 22200000-2231;

E-mail: dr_lizhigang@163.com

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