

The Paravalvular Leak Device

Occlutech® PLD

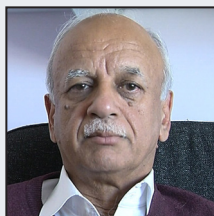


About Paravalvular Leaks: (PVLs) are a significant complication after valve replacement. Approximately 1% to 5% of patients undergoing mitral or aortic valve replacements experience PVLs of various severities, ranging from asymptomatic and benign to life-threatening. Depending on leak size, regurgitation can cause congestive heart failure and pulmonary edema, can increase the risk for endocarditis, and often provokes mild to substantial, transfusion-requiring hemolysis. Redo surgery has been considered the first choice to treat PVLs but carries a higher operative risk compared to that of the initial procedure with mortality rates between 4% and 14%. In addition, there is an increased incidence of leakage after redo surgery. Until today there have been no devices available specifically designed and indicated for PVL closure.

Exciting days in UK....

I'm excited to share with you the very first success stories using the Occlutech® PLD Occluder for paravalvular leak closure. The Occlutech® PLD Occluder is the first CE marked device which offers an alternative treatment for paravalvular leak closure in patients after surgical Mitral & Aortic Valve replacement. Especially along those who could not undergo a re-surgery or those who like to avoid a high operative risk the Occlutech® PLD Occluder is the only option to close a paravalvular leak.

Monday, October 6th, Dr. Iqbal Malik - Hammersmith Hospital, London UK - performed the first commercial implantation. A 48 years old male presented a paravalvular leak after aortic valve replacement. NYHA classification of III, leak graded as moderate to severe and a mild hemolysis were observed. The defect could be easily crossed with a hydrophilic wire by Dr. Malik and a 5 mm squared device with waist was placed. The defect was immediately closed after device placement. The patient was discharged without any further complications. Following the successful start in London Dr. Eustaquio Onorato from Italy presented the PLD CE mark Clinical Datas the first time during GISE 2014 in a "New Technology" session. His presentation paved the way for new appointments with existing and new customers who are eager to share in our excitement.



Dr. I. Malik and Prof. Qureshi from London UK - performed different PLD trial procedures and did the first commercial implants

This story could not have been a success without great and extensive team work. I would definitely say thanks to different individuals: Dr. Goktekin - Istanbul, Dr. Malik - London, Prof. Qureshi - London, Prof. Figulla - Jena, Dr. Lezaun - Spain, Dr. Onorato - Italy, Rene Wenmekers & Regulatory Team, S. Demir & R&D Team, L. Havdrup - Marketing, and all other physicians and employees who were involved in PLD procedures & development. Also a big thank you to Shakeel Osman & the UK Team for clinical support as well as to A. Leong & Customer Service Team.

Kind Regards
Andreas Hueske