

# Mitral Butterfly

## 90-day results of the chronic animal model



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### Background

The Mitral Butterfly is a transcatheter device intended for mitral prolapse repair. It consists of a nitinol frame (atrial wing and swing arm), a PET mesh and PTFE yarns. The mesh is attached at the frame and covers the entire prolapsing segment of the valve. It reattaches at the swing arm via PTFE threads, representing an artificial papillary muscle. The aim of this study was to evaluate the long-term behavior of the implant with a focus on the geometric suitability of the implant to the native anatomy, the durability of the device and the ingrowth response from the heart.

### Methods

Prototypes were implanted on pump in six chronic 90d pigs (Yorkshire Cross, 75-85kg range). The implants were deployed by means of a delivery system via the roof of the left atrium.

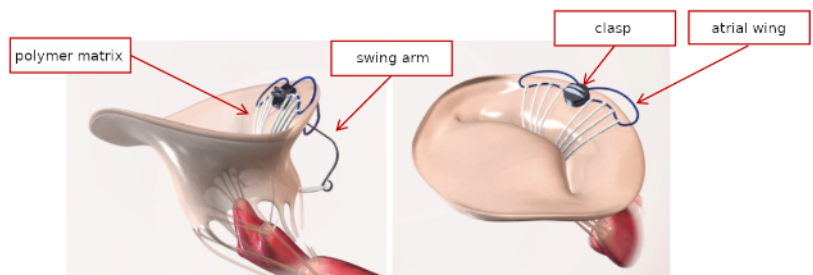


Figure 1: Concept of the device

### Results

Implant deployment was successful in all animals and took 1:20 minutes on average, the mean bypass time was 32:44 minutes. In five pigs, a follow-up period >90 days was reached, one animal was sacrificed after 43 days due to a non-device related issue.

After an average of 10-12 million cycles per pig, the device showed no signs of wear. No signs of tissue abrasion could be detected. Mesh ingrowth was present in all specimens. However, the amount of mesh ingrowth differed significantly at visual inspection.

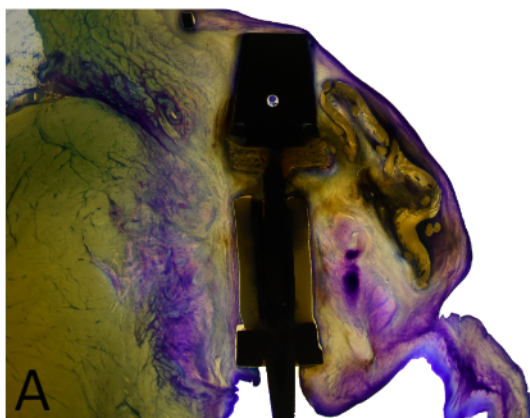
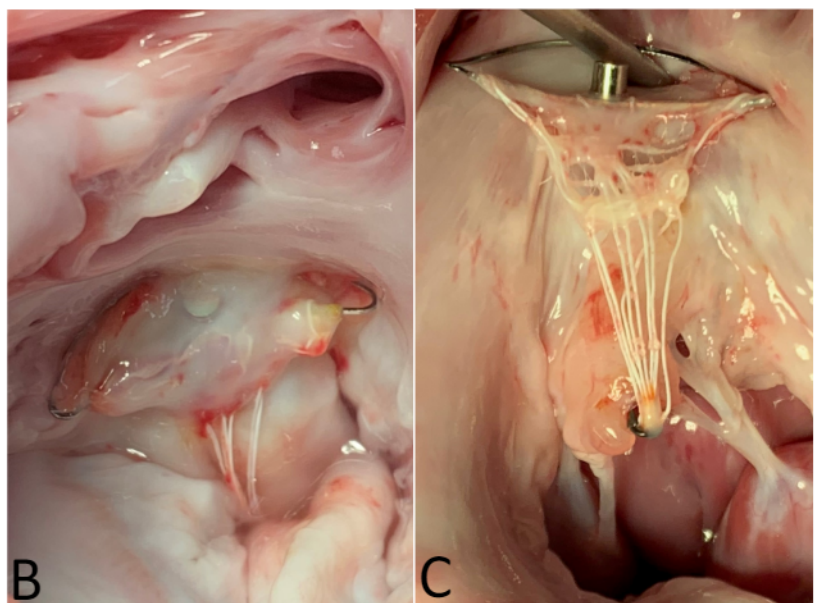


Figure 2:

- A. Histology, 90 days post implant fully endothelialized pin and mesh
- B. Necropsy, 90 days post implant, microporous mesh, major endothelialization.
- C. Necropsy, 90 days post implant, warp knit mesh, minor endothelialization.



### Conclusion

The Mitral Butterfly is a novel mitral valve repair technology. The concept has been proven feasible in this chronic animal study, demonstrating fast implantation and adherence to the native valve.