KINGS COLLEGE LONDON (KCL)

Prototype development of ablation catheter steering technology

THE CHALLENGE

Cardiac arrhythmias affect 2 million people a year in the UK alone, with Atrial Fibrillation being the most common. Arrhythmias which are resistant to early (cardioversion) treatment are treated by catheter ablation to eliminate spurious conduction paths within the heart tissue itself.

The future of this treatment is likely to require ever more precise and sparing delivery, thereby delivering a much-needed boost to success rates whilst retaining greater cardiac function. In order to quickly and efficiently reach specific ablation targets within the heart, KCL had developed a rapid-prototyped steerable ablation catheter model with 3 degrees of freedom and the ability to be guided robotically under MRI imaging, and they needed a partner to develop this technology to the next stage.

THE SOLUTION

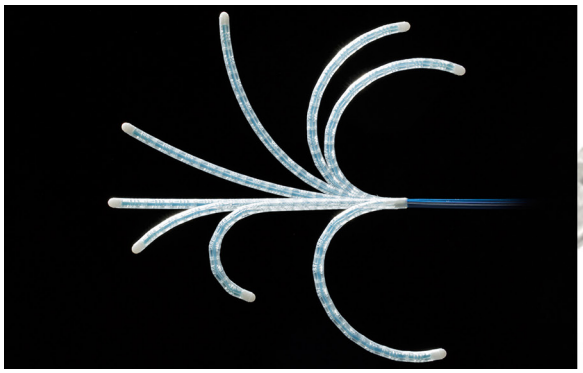
Having selected CDP for our experience in developing catheters and minimally invasive devices, KCL briefed us to progress the rapid-prototyped design to advanced proof-of-concept level with four key objectives:

1. Design for manufacture and assembly (DFMA), including; segment design development and sealing of the catheter from the intracardiac environment.

2. Material selection for mechanical properties, compatibility with sterilisation and MRI, biocompatibility and mechanical perfomance.

3. Catheter steering performance to achieve bend radius, consistency, tip force capacity, deliverability.

4. Whole-catheter design considerations.



We have been delighted with the results of Cambridge Design Partnership's work on this project, their engineering approach and the practical improvements they managed to incorporate. They delivered fully moulded parts, and specified other components and the assembly route which fully met our aspirations for the project

Professor Kawal Rhode, Professor of Biomedical Engineering, King's College London

BENEFIT TO CLIENT

In just 9 months CDP developed the design to meet the challenging brief and address key standards such as ISO 10555 (sterile and single-use intravascular catheters).

The resulting 3mm-diameter catheter has been developed to enable access to all points on the inner surface of the heart chamber via 360 degree steering, tight achievable bend radii, and a steerable section length which is variable in real time - whilst avoiding the requirement for awkward twisting of the catheter shaft. In order to achieve enhanced speed, precision and repeatability it is compatible with MRI navigation and next-generation robotically guided proximal interfaces.

To assure biocompatibility it uses only implantation-grade materials to ISO 10993, and maintains a smooth external profile for reduced risk of clot formation. Compatible with both EtO and Gamma sterilisation, the design allows for scalable manufacture, using proven processes such as micromoulding, extrusion and UV-cure adhesives.

The full-length prototypes we assembled and delivered exceed key regulatory requirements such as the challenging ISO tip pull test, and have enabled KCL to achieve key in-vitro test results - and allowed them to plan for clinical trials.

http://www.kcl.ac.uk/innovation/innovation/Kings-Commercialisation-Institute/index.aspx

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