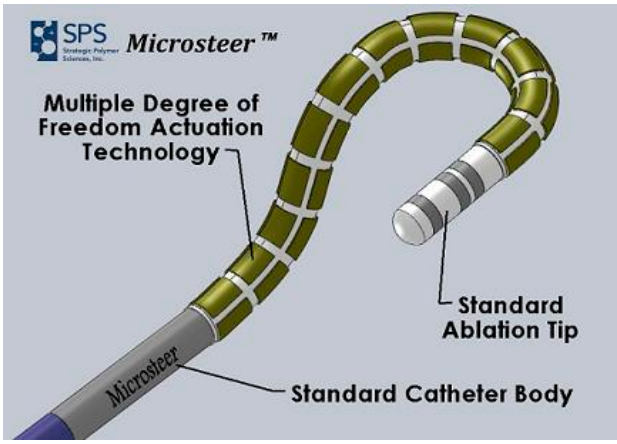
Electroactive Polymer Based Cardiac Ablation Catheters For Greater Flexibility

Strategic Polymer Sciences

Mapping/ablation catheters are used to treat atrial fibrillation. Current mechanical catheters can be difficult and time consuming to operate and hinder reproducible and consistent ablation. This article describes new electroactive polymer (EAP) technology that provides the basis for the development of electronically controlled steerable actuators. The EAP technology will enable standard catheter platforms to incorporate advanced micro-steerability, reduced procedure times and advanced automation capabilities. The innovative electrically steered catheters will benefit millions of Americans who are suffering from atrial fibrillation.



Strategic Polymer Sciences, Inc. [1] (SPS) is developing electrical micro-steerable actuators with micro-articulation capability for the integration with ablation catheters for the treatment of Atrial fibrillation (AFib). Arrhythmias are among the most common disorders of the heart and AFib is the common arrhythmia associated with significant morbidity. AFib can lead to angina, heart failure and stroke. There are currently more than 2.5 million Americans suffering from AFib and there are about 160,000 new cases diagnosed each year. The lifetime risk for the development of AFib is an estimated 25 percent of Americans older than forty. Treatment of AFib is essential for the patient suffering from severe and frequent episodes of these arrhythmias. Ablation catheters are used to treat both ventricular and supraventricular arrhythmia, and there is emerging evidence that the ablation catheter treatment of arrhythmias is curative whereas drug therapy and implant treatments are not curative. Although the catheter ablation is expensive, the cost is still less over time than the cost of drug therapy or surgical interventions. Based on recent clinical trial results, it has been recommended that “ablation should not be reserved as a last resort treatment but is appropriate to consider, in some cases, as first-line therapy.” However, among the more than 2.5 million AFib patients

currently in the US, less than 1 percent are treated with an ablation procedure due to functional limitations of current commercial cardiac catheters. Specifically, due to the lack of reproducibility and precision in controlling the catheter tip position by the push/pull cable in current catheters, the current ablation procedure requires a long procedure time (2 to 9 hours), which subjects physicians and staff to prolonged X-Ray radiation exposure, as well as to the ergonomic challenge of standing for the duration of the procedure. Although ablation procedures are minimally invasive, long procedure times mean an increased risk to the patient as well.

Electro-active polymer (EAP)-based electrical micro-steerable actuators utilize a breakthrough solid state actuator technology, invented by one of the co-founders of Strategic Polymer Sciences, to manipulate the catheter tip position. The linear correspondence between the applied voltage and the dimension change in the EAP actuator enables precise control of the catheter tip and its force level, resulting in a significantly reduced procedure time with the added benefit of a programmable operation capability. This allows for remote operation, thereby reducing the physician’s exposure to radiation. The ease of integration of the proposed actuation technology with current catheter designs will reduce risk and time to market.

Steerable catheters perform the function of mapping and ablating, which requires precise control of:

1. The catheter tip position,
2. The force level at the tip, and
3. The ability of the tip to reach all the required locations in the heart.

The mapping and ablation procedures are time consuming and challenging. The success and efficiency of current procedure are largely determined by the skill of the operator who uses the manually controlled catheters with limited flexibility and maneuverability.

Currently, there are active and extensive development activities regarding improving catheter technologies. For example, using a multi-sensor array on the tip of the catheter can shorten mapping time. Steering the catheter tip to the desired position, however, is the first step in an intracardiac electrophysiological study (EPS) and is critical to the efficiency and success of the whole procedure. Strategic Polymer Sciences is developing a steerable actuator tube made from advanced proprietary EAP-based actuators to replace a portion of the catheter sheath and the mechanical push/pull cables inside the current catheters. The new steerable actuator tube will be built as a module that can be seamlessly integrated with the current mapping and ablation electrical modules. Since the EAP-based actuators can be remotely steered with electrical signal controlled by a computer, the steerability, steering precision and procedure time can be significantly improved.

While the proposed EAP-based micro-steerable catheters have marked advantages over current catheters steered manually with push/pull cables, there are two recently developed steerable catheter technologies, namely sophisticated robotic systems and magnetically steered systems. Although the physician can remotely

control the robotic systems, these systems cannot reach all the heart chambers due to their bulky size. In the magnetic systems, because a magnetic field gradient originating from magnets outside of the body creates the force exerted on the catheter tip, the force level is low and consequently it has low load capability. As such, ablation lesions are often not deep enough and ablation points must be redone manually to create the necessary lesion depth. The SPS micro-steerable actuator based catheters largely avoid these issues.

From the EP perspective, “new ablation technologies need to show shorter procedure times, increased efficacy, and improved safety in order to drive widespread adoption.” SPS’s electrically, micro-steerable catheters will combine the high strain, tunable force levels (via electric signals), and computer controllability, which represents a revolutionary approach.

There are several ways in which the SPS design’s potential is acknowledged to benefit EP physicians and their patients. Because of the electrically actuated nature of this technology, the actuator system can be operated remotely to reduce the radiation exposure of the procedure operators. In addition, the extremely resolute level of spatial control and positioning repeatability lends itself to quicker positioning of the catheter tip for mapping and ablating with the potential to significantly reduce the procedure time. Furthermore, this enhanced position control suggests that physicians with broader range skill levels may be able to effectively operate the catheter creating the opportunity to treat more patients over time. Finally, the piezoelectric feature of SPS’s EAP can also be used as a force transducer to monitor the force at the catheter tip, providing feedback to avoid damaging the cardiac tissue. SPS EAP actuation technology in a mapping and ablation catheter form has the potential to accommodate all of the above requirements, and makes these procedures available to a wider group of patients giving them access to treatments, which previously have been due largely to cost and time.

Links:
[1] http://www.strategicpolymers.com/