About Atrial Fibrillation

Atrial fibrillation (AFib) is the most common irregular heartbeat and a potentially deadly disorder. It occurs when abnormal signals travel from the pulmonary veins (PV) to the top chambers of the heart, the atria. AFib is associated with a five-fold increased risk for stroke and an increased risk for left ventricular dysfunction, congestive heart failure and cardiovascular hospitalizations; and a two-fold increase in mortality. There are an estimated 30 million individuals worldwide diagnosed with AFib, 5 million in the US. Globally, 300,000 receive an ablation annually, 150,000 in the US.

How AFib is treated today

One treatment for AFib is ablation, the destruction of tissue by burning (with various energy sources) or freezing (cryoablation). Ablation catheter systems today consist primarily of either “point-by-point” ablation devices or a “balloon.” Ablation procedures create a lesion (scar tissue) to block abnormal electrical signals from passing from the PVs to the atria in the beating heart. The ablation procedure performed is called pulmonary vein isolation (PVI). This is accomplished by generating continuous, long-lasting, transmural (through the heart wall) lesions around the PVs. A successful PVI reduces or eliminates the burden of AFib for patients. Unfortunately, AFib recurrence is observed in about 30% of patients at one year post-ablation.

AblaCor’s™ solution: CircumBlator™ delivers the “single-shot” PVI ablation physicians are seeking

❤ Unique flow-through anchor and discrete electrode array
❤ The anchor stabilizes the electrode array for optimum tissue contact around the PV
❤ Consistent tissue contact yields precise energy delivery for continuous, durable lesion creation in a single procedure
❤ Ablation and feedback capabilities all in one catheter
❤ Feedback helps the physician verify lesion quality

The CircumBlator™ system is not approved for human use.
Recurrent AFib observed in 30% of patients after procedures with current technologies

Current ablation technologies frequently fail to maintain conduction block after ablation treatment. Insufficient contact fails to destroy tissue through the heart wall and/or along the lesion. This often leaves gaps in the lesions. Irregular electrical signals can travel from the PVs through the gaps into the left atrium, causing electrical reconnection of the PVs and recurrence of AFib. Current devices do not consistently stabilize the ablation catheter against the heart tissue around the PVs, requiring the physician to manually apply contact during the ablation cycle. Making this even more complicated, the procedure is performed in the beating heart. Thirty percent of patients have recurrence of AFib in the first year after ablation.

The CircumBlator system is designed to be superior to current devices.

CircumBlator is designed to offer a durable (long-term) solution to PVI ablation. The table below shows how the “single-shot” CircumBlator is unique from current “point-by-point” and “balloon” ablation devices.

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<tr>
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<th>CircumBlator™</th>
<th>Point-by-Point</th>
<th>Balloon</th>
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<tbody>
<tr>
<td>Anchor stabilizes electrode-tissue contact</td>
<td>✓</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Precise, controlled energy delivery</td>
<td>✓</td>
<td>X</td>
<td>X</td>
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<tr>
<td>Consistent lesions encircling PVs</td>
<td>✓</td>
<td>X</td>
<td>X</td>
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Professor of Medicine,
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“Ablacor’s novel approach of a circular ablator, with its controlled electrode-tissue contact, designed to generate continuous and transmural ablation lesions reliably, holds great promise and would be a major advance.”

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