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To whom it may concern,

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Japan Lifeline Receives Regulatory Approval for HeartLight X3

Japan Lifeline Co, Ltd. is pleased to announce that it has received regulatory approval on June 17, 2021 for the HeartLight X3, a next-generation of the HeartLight endoscopic laser ablation system manufactured by CardioFocus, Inc. Japan Lifeline has been an exclusive distributor of the HeartLight System in Japan since 2018. The HeartLight X3 will be reimbursed under the National Health Insurance in August of this year and the commercial launch is to follow.

The first-generation HeartLight is the world's first ablation system that incorporated laser energy and an endoscope for the ablation treatment of atrial fibrillation (pulmonary vein isolation) and this balloon technology was introduced by Japan Lifeline in 2018. Using the HeartLight System, physicians can directly visualize the target site with an endoscope, and the laser energy can be titrated in accordance to the anatomy while performing segment-by-segment ablation. In Japan, ablation performed using laser energy has been reported to have good clinical results which were demonstrated by a report that the non-recurrence rate of atrial fibrillation after one year was 82.1%.[1]

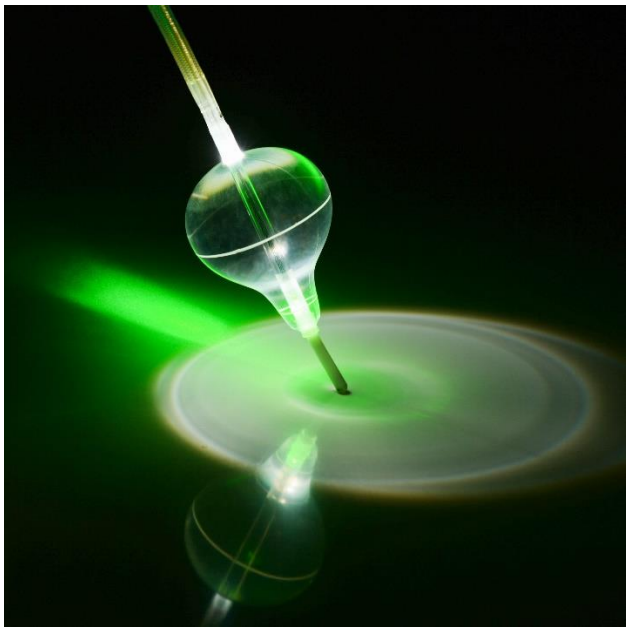
In addition to the first-generation's concept of combining laser energy and an endoscope, the HeartLight X3 has a new ablation mode called "RAPID Mode." RAPID mode significantly reduces the procedure time, which was comparable to radiofrequency ablation with the first-generation. In RAPID mode, the laser energy automatically rotates with a motor control system to create continuous circumferential lesions. This helps reduce the procedure time drastically from two to three hours with the first-generation to about one hour.[2]

The HeartLight X3 also features significant improvements in the balloon compared to the first-generation. The new balloon has significantly improved compliance, allowing it to fit into various shapes of pulmonary veins. In addition, with the new compliant balloon, the amount contact with the myocardium has been greatly improved. This will help balloon stability throughout the procedure and contribute to improve procedural efficiency.

Having EP/ablation business as its core, Japan Lifeline has been working to strengthen its therapeutic portfolio as a priority in addition to the diagnostic business, where the company already has strong market presence. As part of this effort, Japan Lifeline successfully introduced the HeartLight System to a widespread of medical institutions in Japan. By launching the next-generation HeartLight X3, which improves the procedural efficiency without compromising the efficacy, Japan Lifeline intends to expand the therapeutic portfolios and strive for more growth of its EP/ablation business.

[1] Clinical results of an observational study of the first-generation HeartLight (304 cases at 21 sites) in Japan (The 85th Annual Meeting of the Japanese Circulation Society LS14)

2 Boris Schmidt, Jan Petru, K.R. Julian Chun, Lucie Sediva, Stefano Bordignon, Shaojie Chen, Petr Neuzil, et al; Pivotal Study of a Novel Motor-Driven Endoscopic Ablation System; Circ Arrhythm Electrophysiol. 2021;14:e009544. DOI: 10.1161/CIRCEP.120.009544



HeartLight X3 Catheter

About CardioFocus, Inc.

Headquartered in Marlborough, MA, CardioFocus is a medical device innovator and manufacturer dedicated to advancing ablation treatment for cardiac disorders such as atrial fibrillation (AFib), the most common heart arrhythmia. The HeartLight X3 catheter, endoscope, sheath, console and balloon fill media are all manufactured in the USA. For more information, visit http://www.CardioFocus.com.