

Hyperflex balloon catheter by Endovastec receives marketing approval in Japan

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Shanghai MicroPort Endovascular MedTech has received registration approval from Japan Pharmaceuticals and Medical Devices Agency (PMDA) for its independently-developed Hyperflex Balloon Catheter (Hyperflex) as the company's first product approved for marketing in Japan. Hyperflex obtained CE Mark in 2016 and is already available in overseas markets in South America and Asia.

Hyperflex is intended to assist in the dilation of aortic stent graft. It uses a compliant TPU balloon to expand the deployed stent graft, which enables improved adherence to the vascular wall, minimizes type I/III endoleaks, and improves stent positioning for better short- and long-term outcomes. When used in conjunction with the aortic stent graft system, Hyperflex provides an integrated endovascular aneurysm repair (EVAR) solution, making it easier and more flexible.

Qing Zhu, President of Endovastec, stated, "The approval of the Hyperflex Balloon Catheter in Japan signals a growing acceptance of our EVAR devices in more and more national and regional healthcare systems, paving the way for the company's continued marketing in Asia and the globe. Endovastec™ will continue to innovate to improve solutions for aortic diseases and reach more patients worldwide with better products and services."