

P+F Products + Features GmbH gains CE Mark approval for TricValve® Transcatheter Bicaval Valves System

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TricValve® Transcatheter Bicaval Valves System made in Europe

Today P+F Products + Features GmbH announced that it achieved the CE Mark for its medical device, the TricValve® Transcatheter Bicaval Valves System. It is the first bicaval transcatheter valve system worldwide that has been accredited with the CE Mark. Besides the CE Mark the TricValve has been granted the FDA Breakthrough Device Designation in December 2020, thus confirming the uniqueness of the device. The TricValve® Transcatheter Bicaval Valves is a system of two self-expanding biological valves for the treatment of patients with hemodynamically relevant tricuspid insufficiency and caval reflux.

“It is a huge milestone to receive the CE Mark for the TricValve®. This could be a big change in the treatment of patients with hemodynamically relevant tricuspid insufficiency and caval reflux.”, said CEO of P+F, Dr. Katharina Kiss.

About the TricValve® Transcatheter Bicaval Valves System

The two dedicated bioprostheses are implanted percutaneously into the inferior and superior vena cava without disturbing the native tricuspid valve.

They are especially intended for use in patients at extreme risk or who are inoperable for open heart surgical therapy. P+F uses exclusively its proprietary “Dry Pericardium”, which enables the TricValve® Transcatheter Bicaval Valves System to come fully pre-mounted, thus facilitating the use of this innovative device in daily clinical practice.

About P+F Products + Features GmbH

P+F is a leading European company in structural heart disease. With more than 25 years of experience in the medical field, the leadership team of P+F has built up a complete infrastructure for research, development, manufacture, and distribution in order to deliver significant innovations and add value to its customers and patients. P+F is striving to become the “standard of comparison” in the development of state-of-the-art innovative technologies in the field of cardiology.

The further pipeline includes transcatheter biological heart valves like the TAVI system Vienna Aortic Self-Expandable Transcatheter Valve, a Pulmonary Valve and Mitral Valve as well as Aortosave®, a minimally invasive device to treat Type A aortic dissections, as well as the full portfolio of endovascular grafts. The proprietary Dry

Pericardium technology platform enables off the shelf use of the company's heart valves.

Headquartered in Vienna, Austria, P+F has different production sites in Europe, Asia and Brazil. Worldwide operations are coordinated by Dr. Katharina Kiss, CEO, and Dr. Siegfried Einhellig, President and COO. P+F has recently entered into Joint Ventures with OrbusNeich® for the APAC region as well as with Relisys Medical Devices Ltd. for the Indian subcontinent and neighbouring countries.

For more information, please visit <https://productsandfeatures.com>.

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