

Press Release

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SIS Medical AG receives FDA 510(k) approval for its lead product, OPN NC[®] TWIN-Wall Super High Pressure PTCA Balloon

SIS Medical AG (Swiss Interventional Systems), a globally leading developer, manufacturer and distributor of high-quality and high-performance products in the field of interventional cardiology, announces the approval by the U.S. Food & Drug Administration of its lead product **OPN NC Super High Pressure PTCA Balloon Catheter** under 510(k) number K212393.

The OPN NC balloon utilizes an unique double balloon (TWIN-Wall) technology invented by SIS Medical AG, providing a super high pressure resistance with a rated burst pressure of 35 atm with a very low compliance. These performance features allow for a perfect preparation of challenging lesions prior to stenting without over-dilating of the blood vessel. The device can also be applied for post-dilatation of under-expanded stents.

“This is a very significant milestone in our strategy to establish SIS Medical’s entry in the important international markets. Since the market introduction in Europe, already more than 100,000 patients have been successfully treated with OPN NC. We are convinced that US cardiologists will appreciate the benefit of our innovative and internationally recognized balloon technology for their patients. The access to the US market will greatly accelerate the further development, reputation, and international growth of SIS Medical AG”, says Sergej Kammerzell, CEO of SIS Medical AG.

Ron Waksman MD, Interventional Cardiologist at MedStar Washington Hospital Center and member of SIS Medical’s Advisory Board states: “We have been waiting for this product already for a long time and we are looking forward to start using it soon in our daily practice. OPN NC carries a unique feature utilizing ultra high pressure to optimize PCI outcomes. Additionally, it is an important addition to our armamentarium for high complex lesions such as in-stent restenosis and undilatable lesions”.

“The rather simple FDA sentence in the clearance letter: ‘You may, therefore, market the device (OPN NC) ...’, opens the worldwide largest market in United States for our OPN NC product. We will now establish the US distribution and keep walking our path with the same pace, passion, and dedication to quality in the future. Registration activities in China and Japan have been started and approvals will come within the next years”, adds Willi Zwahlen, VP Sales & Marketing, Founder and Board Member of SIS Medical AG.

“There is a huge potential for the OPN NC TWIN-Wall Super High Pressure Balloon in the market. A realistic view on the indications shows that the annual demand for the innovative SIS Medical balloon could reach one million clinical applications worldwide within the next few years. Considering the ease of use and effectiveness of OPN NC, this will provide a better care to many patients. My special thanks goes to the entire team of SIS Medical AG, for their great job”, says Hubertus Leonhardt, Chairman of the Board of SIS Medical AG and Managing Partner of Tuebingen based medical technology investor SHS Beteiligungsmanagement mbH.

About SIS Medical AG

SIS Medical AG, based in Frauenfeld, Switzerland, is a leading Swiss developer, manufacturer and distributor of high-quality and high-performance PTCA balloons. The company is very well known in the field of interventional cardiology for its lead product “*OPN NC TWIN-Wall Super High-Pressure PTCA Balloon*” which allows the treatment of challenging coronary lesions and the optimization of the stent results.

<https://www.sis-medical.com/>

The company is privately owned and the major shareholder, SHS Gesellschaft für Beteiligungsmanagement mbH (www.shs-capital.eu), located in Tuebingen, Germany, is represented in the Board of Directors by Hubertus Leonhardt, Managing Partner at SHS.

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