

Press Release

Frauenfeld, Switzerland

26th of October 2025

Super-High-Pressure NC balloon (OPN) is non-inferior to Intravascular Lithotripsy (IVL) balloon catheter for lesion preparation and stent expansion in severely calcified lesions during percutaneous coronary intervention (PCI)

San Francisco, October 26th of 2025. During the late-breaking clinical trial session at the TCT congress from the Cardiovascular Research Foundation (CRF) the results of the VICTORY clinical trial were presented. The randomized, multi-center clinical study was designed to compare the safety and efficacy between the OPN and IVL devices for lesion preparation and optimized stent expansion in highly complex calcified coronary lesions, deploying a drug-eluting stent (DES). Coronary artery calcium affects approximately one-third of patients undergoing PCI and is a key contributor to procedural and stent failure.

A total of 282 patients at three sites in Switzerland and Canada were randomized one-to-one to IVL (n=142) and OPN (n=140). The primary endpoint was final stent expansion assessed by optical coherence tomography (OCT) determined by an independent imaging core laboratory. The OPN group achieved a median of 85.0% stent expansion compared to 84.0% in the IVL group, meeting non-inferiority (95% CI: 82.5-87.5, $p < 0.0001$). The use of OPN resulted in similar rates of acute procedural (98.6% versus 97.1%) and strategy success (98.6% for both) compared with IVL. The results were consistent across a number of patient subgroups.

In addition, there were no significant differences in safety outcomes including coronary artery dissections, perforations, or side branch occlusions. "This study clearly shows that utilizing an OPN NC is non-inferior to IVL for OCT-guided lesion preparation and stent expansion in severely calcified lesions," said Matthias Bossard, MD, Head of CHIP & CTO-PCI Program at Luzerner Kantonsspital Heart Center. "With similar safety profiles, the OPN NC can be a feasible and faster alternative to IVL."

About the VICTORY clinical trial

VICTORY Trial – A randomized, multicenter, non-inferiority comparison of Shockwave Intravascular Lithotripsy (IVL) and the OPN non-compliant balloon for treatment of calcified and refractory coronary lesions.

About SIS Medical

SIS Medical AG, based in Frauenfeld, Switzerland, is specialized in developing, manufacturing and distributing cardiovascular products for interventional arterial diseases. The company is known for its main product OPN NC, a Super-High-Pressure PTCA Twin-wall Balloon, for the treatment of calcified and complex calcified lesions and in-stent restenosis.