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ADVANCED BIFURCATION SYSTEMS MOTHER-DAUGHTER PLATFORM IN TREATMENT OF COMPLEX CORONARY BIFURCATIONS: PROSPECTIVE, MULTICENTER FIRST-IN-MAN FEASIBILITY EXPERIENCE

i2 Poster Contributions

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Background: Dedicated bifurcation stenting devices are provisional side-branch, or ostial stents with one or more limitations: proper alignment, tissue coverage, loss of wire access, wire wrap and arduous procedures requiring additional devices and steps for completion. The ABS modular system ensures automatic alignment of the mother (main branch) and daughter (side branch) stents with complete tissue coverage and guaranteed side-branch access. We present the first human implantations and angiographic follow-up of this unique platform.

Methods: This was a prospective, non-randomized, multi-center trial evaluating the safety, technical feasibility and acute efficacy. Patients with de novo native coronary artery stenosis involving a bifurcation, who met the inclusion and exclusion criteria, were enrolled. The primary endpoint was 30-day composite MACE. Secondary endpoints include procedural success and safety at 6 months. Angiographic follow-up was performed at 6 months to assess binary restenosis for the target lesions.

Results: A total of 10 devices were implanted. The ABS Full Bifurcation Stent (MD-Bi) was implanted in 7, and the provisional side-branch stent (MD-P) was implanted in 3 patients, Left anterior descending-Diagonal (n=5), Left Circumflex-Obtuse marginal (n=3), and Posterior descending artery-Posterior lateral branch (n=2). The average patient age was 58. The 30-day composite MACE and TVR was 0%. Procedural success was 100% with no residual stenosis. IVUS revealed full stent apposition and complete coverage.

6 month composite MACE has remained 0%. All patients are free of angina. Angiographic follow-up to date has revealed no restenosis at the bifurcation and edge restenosis in 2 daughter vessels.

Conclusion: The ABS Bifurcation Stent Delivery System is a novel stent platform designed to simply and reproducibly permit stenting in any clinically significant bifurcation lesion regardless of vessel location or geometry. This first-in-human implant study provides preliminary evidence of feasibility, and short-term efficacy. Additional long-term and larger scale studies are needed to further validate this unique device.