PRESS RELEASE

Landmark Results from S-FLEX UK-II Registry Published in BMJ Open: Supraflex Cruz Demonstrates Outstanding Performance

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SMT (Sahajanand Medical Technologies), a global leader in cardiovascular devices, is pleased to announce the publication of groundbreaking findings from the S-FLEX UK-II Registry in BMJ Open. This large-scale, multicentre study highlights the safety and efficacy of SMT's ultrathin Supraflex Cruz sirolimus-eluting stent (SES) in a real-world, all-comer UK patient population, particularly in high-risk subgroups.

Conducted across 19 sites in the United Kingdom, the prospective, observational study enrolled 1,835 patients requiring percutaneous coronary intervention (PCI) between March 2020 and September 2021. The S-FLEX UK-II Registry provides significant real-world insights into the performance of Supraflex Cruz SES, solidifying its role as a leading drug-eluting stent (DES) choice in complex coronary artery disease (CAD) management.

Key Study Findings –

- **Study Design**: Prospective, observational, multicenter registry across the UK
- **Patient Population**: Real-world, all-comers requiring PCI, including complex and high-risk subgroups
- **Follow-Up**: 12 months (data presented at TCT 2023)

Primary **Follow-Up** Endpoint: Target Lesion Failure (TLF), a composite of cardiac death, target vessel myocardial infarction (TV-MI), and clinically indicated target lesion revascularization (CI-TLR)

Superior Clinical Performance in High-Risk Subgroups

The S-FLEX UK-II Registry reported exceptionally low rates of TLF and stent thrombosis, reinforcing Supraflex Cruz's position as a best-in-class stent**.**

At 12 months, the study observed:

- CI-TLR rate: 0.8% (n=15)
- Overall stent thrombosis rate: 0.3%
- TLF rate in high-risk subgroups:
- Diabetes mellitus: 6.2% TLF, 1% stent thrombosis
- Bifurcation lesions: 1.8% TLF, no stent thrombosis
- Type B2/C lesions: 2.5% TLF, 0.3% stent thrombosis
- Long lesions (>20 mm): 2.7% TLF, 0.3% stent thrombosis

Prof. Azfar Zaman, Freeman Hospital, Newcastle Upon Tyne, United Kingdom, and Principal Investigator of the study stated, "The overall study results show consistently high device success rates and low clinical event rates with Supraflex Cruz in a real-

world all-comers population from the United Kingdom. Importantly, the safety of Supraflex Cruz was once again confirmed in high-risk subsets of patients and lesion types."

Dr. Vellore J Karthikeyan, first author on the study report, summarized the findings of the trial, "These data reinforce the safety and effectiveness of the Supraflex Cruz SES in complex PCI cases including diabetes, bifurcation, complex, and long lesions, showcasing its superior performance in managing CAD patients with challenging anatomical characteristics. As an interventional operator, it is pertinent to also highlight the procedure related characteristics of the stent, particularly its deliverability and visibility on fluoroscopy."

This study further builds upon previous successful outcomes observed with Supraflex Cruz. In the Cruz-HBR Registry, the stent demonstrated superior results compared to biolimus-coated stents in high bleeding risk (HBR) patients. Additionally, the recently published FIRE trial (2023) showed a significantly reduced risk of adverse events in elderly patients (≥75 years) with multivessel CAD using Supraflex Cruz in a physiology-guided, complete revascularization strategy, versus culprit-only revascularization. Further, the recently published COMPARE 60-80 randomized controlled trial in HBR patients demonstrated non-inferiority of Supraflex Cruz to Ultimaster Tansei, and numerical superiority in a number of clinically relevant endpoints.

SMT's Chief Medical Officer Dr Krishna Sudhir commented, "This study confirms the benefits of using Supraflex Cruz in an all-comers population, with excellent outcomes for the complex subsets of patients. With ever more challenging morphology for clinicians to treat, this provides an important option for these patients and further adds to the large body of evidence for Supraflex Cruz."

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The S-FLEX UK-II Registry thus confirms the Supraflex Cruz SES as a leading choice for high-risk PCI cases, offering class-leading outcomes in real-world patients.

About SMT (Sahajanand Medical Technologies)
SMT is a global leader in cardiovascular medical devices, specializing in drug-eluting stents and structural heart disease solutions. Operating in over 80 countries, SMT is dedicated to advancing patient care through innovative medical technologies and clinical excellence, as demonstrated by the Multivessel TALENT trial. SMT has achieved recognitions from the Ministry of Health Sciences & Technologies for its tremendous contributions in the field of coronary healthcare. SMT also pioneered the introduction of biodegradable polymers in the cardiovascular segment.

About Supraflex Cruz

The Cruz design provides physicians access to difficult and tortuous lesions which are particularly challenging in their practice. The stent retains all the benefits of Supraflex stents or the previous "Supra" family of stents, viz, a blend of proprietary biodegradable polymers to release the drug, high radial strength, and low crossing profile. Supraflex Cruz has a large and extensive size matrix, covering diameters from 2.0 to 4.5 and lengths from 8 mm to 48 mm. This size matrix ensures no compromises in the coronaries for either physician or patient.

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