



Alliance DeNovo Clinical Study

The ALLIANCE Registry¹, presented at TCT 2025, is a Japanese prospective, non-randomized, multicenter, all-comers de novo registry of over 1,800 patients including over 1,300 patients treated with AGENT™ DCB.

Alliance All-Comers De Novo Registry Study Design

Prospective, non-randomized, multicenter, all-comers *de novo* registry of
n = 1,817 patients², included after successful lesion preparation

Stand alone or DES+DCB strategy

DCB
n = 1,592 (88.7 %)

Hybrid
n = 202 (11.3 %)

Image guided PCI was performed on 90% of patients (87% with IVUS), with only 1.1% bailout stenting

Primary Endpoint: Target Lesion Failure at 1-year

Primary Endpoint: The trial met its primary endpoint 1-year Target Lesion Failure (TLF) rate of 4.7 % which was significantly lower than the prespecified performance goal of 7.5 % (p < .001)²

Primary Endpoint
4.7%
TLF rate at
1-year

0.4%
TV-MI at
1-year

2.9%
Clinically driven
TLR at 1-year

The TLF was driven by low clinically-driven Target Lesion Revascularization (TLR) at 2.9% and Target Vessel Myocardial Infarction (TV-MI) at 0.4%

In ALLIANCE, the excellent outcomes in a complex de novo patient population, may represent a model for achieving optimal DCB outcomes with a modern PCI approach. This study is more representative of real-world practice.

¹ Data presented at TCT 2025 by Dr. Masato Nakamura. Results include over 1,300 Japanese patients treated with AGENT DCB (73.3% of the 1,800 PTX DCB patients)

² Devices used in this study: AGENT 73.3% / SeQuent Please Neo 26.4%

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