



# Alliance DeNovo Clinical Study

The ALLIANCE Registry<sup>1</sup>, 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 patients<sup>2</sup>, 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)<sup>2</sup>

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.**

<sup>1</sup> 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)

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

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