

PRAETORIAN DFT Trial



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The PRAETORIAN DFT trial is a global, prospective, randomized trial to test the hypothesis that omitting VF conversion testing in patients undergoing de novo S-ICD implant, when guided by the PRAETORIAN score, is non-inferior to performing VF conversion testing.¹

► PRAETORIAN SCORE

The PRAETORIAN score is a validated, non-invasive method to evaluate S-ICD positioning via PA and lateral chest X-ray after the procedure.^{2,3} As demonstrated in the PRAETORIAN DFT trial sub-analysis, among PRAETORIAN scores less than 90, VF conversion testing during implant was successful 99% of the time.³

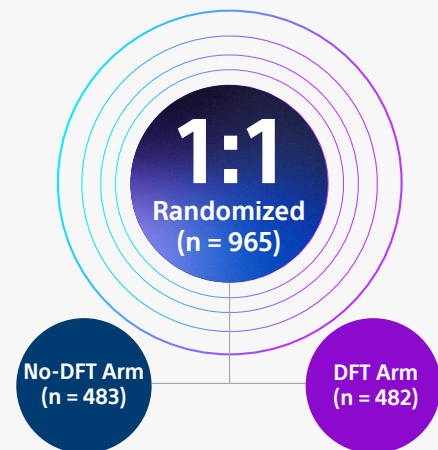
► The PRAETORIAN DFT trial is sponsored by Academic Medical Center (AMC) in Amsterdam. Funding for the trial is provided by Boston Scientific.

Note: In this trial, DFT testing is synonymous with VF conversion testing during implant.

► ENROLLMENT AND OBJECTIVE

A total of 965 patients were randomized 1:1 to their respective arms and were included in the endpoint analysis – S-ICD implantation with DFT (n = 482) or S-ICD implantation without DFT (n = 483) – and were followed for a median of 41 months.^{1,4} Patients with PRAETORIAN scores greater than or equal to 90 had a protocol-defined indication for DFT.^{4,5}

Previous trials studying primary prevention patients with de novo TV-ICD devices, such as the NORDIC and SIMPLE trials, demonstrated that omitting DFT testing was non-inferior to performing DFT testing and did not lead to improved shock efficacy nor impact mortality.^{6,7} The primary objective of the trial is to determine whether omitting DFT testing during S-ICD implantation is non-inferior to performing DFT testing when the postoperative position of the system is confirmed by assessment of the PRAETORIAN score.¹

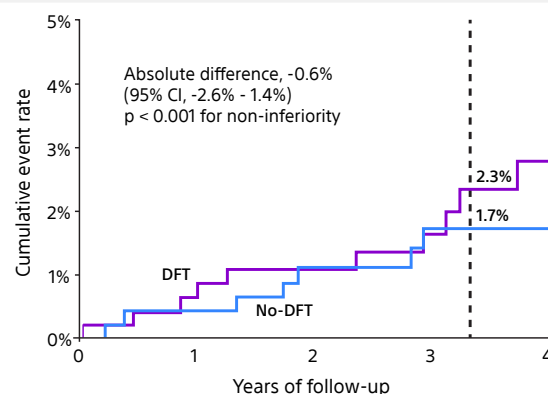


■ Primary endpoint met

The PRAETORIAN DFT trial met the primary endpoint by demonstrating non-inferiority ($p < 0.001$) of omitting VF conversion testing in patients undergoing de novo S-ICD implant when guided by the PRAETORIAN score. **Both arms experienced very low first failed shock conversion of spontaneous arrhythmias.**^{4,*}

Almost all patients (96.8%; n = 459/474) in the no-DFT arm had PRAETORIAN scores less than 90.⁴

First failed shock conversion of spontaneous arrhythmias



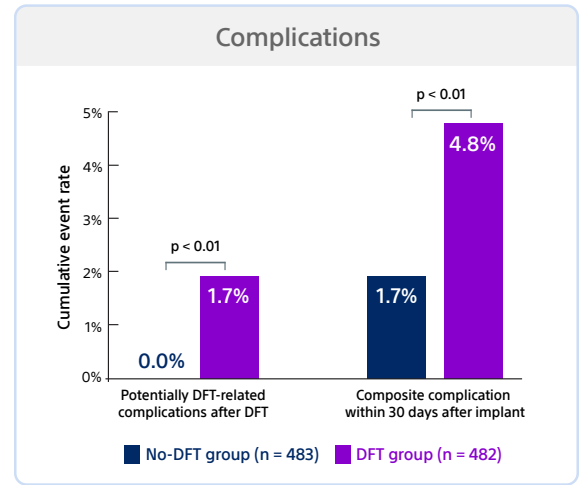
This is the first long-term, randomized trial to evaluate omitting VF conversion testing during the S-ICD implant when guided by the PRAETORIAN score. Investigators found that omitting VF conversion testing, when the S-ICD system position is confirmed using the PRAETORIAN score, **simplified the procedure, reduced complications and found no increase in first failed shocks or S-ICD revisions post implant.**^{4,5,*}

► COMPLICATION RATES, SHOCK EFFICACY, MORTALITY AND S-ICD REPOSITIONS

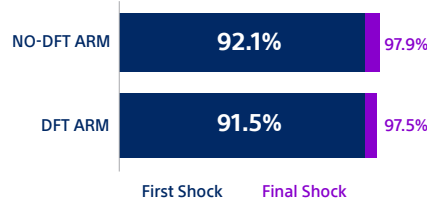
Complication rates were lower in the no-DFT arm compared to the DFT arm.

After DFT testing | the potentially DFT-related complication rate in the DFT arm was 1.7% compared to zero in the no-DFT arm ($p < 0.01$).^{4,5}

Within 30 days | of S-ICD implant, the composite complication rate was significantly higher in the DFT arm compared to the no-DFT arm ($p < 0.01$).^{4,5}



In the no-DFT arm, first and final shock efficacy was 92.1% and 97.9%, respectively.⁴ In the DFT arm, first and final shock efficacy was 91.5% and 97.5%, respectively.⁴ **First and final shock efficacies in the PRAETORIAN DFT trial are similar to previous large S-ICD trials.**⁸⁻¹¹



While numerically lower in the no-DFT arm, there was **no statistically significant difference in all-cause mortality and arrhythmic death.**^{4,5}

	No-DFT (n = 483)	DFT (n = 482)	HR (95% CI)
All-cause mortality	35 (7.2%)	39 (8.1%)	0.9 (0.6-1.4)
Arrhythmic death	1 (0.2%)	3 (0.6%)	0.4 (0.04-3.4)

Intraoperative repositions were higher in the no-DFT arm compared to the DFT arm and the differences were not statistically significant.^{4,5}

	No-DFT (n = 483)	DFT (n = 482)	HR (95% CI)
Intraoperative repositioning	23 (4.8%)	15 (3.1%)	1.55 (0.80-3.08)

► ACHIEVING A LOW PRAETORIAN SCORE IN CLINICAL PRACTICE

Advancements in S-ICD implant techniques — the intermuscular technique and two-incision approach — have improved implant outcomes that support optimal generator placement, simplified procedure and help achieve a low PRAETORIAN score (< 90).¹²

- The intermuscular pocket minimizes any adipose tissue between the S-ICD device and thoracic wall and positions the device in a posterior placement on or near the midline, reducing the risk of anterior placement and contributing to a low PRAETORIAN score.^{12,13}
- As found in the S-ICD RHYTHM DETECT Registry, the two-incision technique was associated with a low PRAETORIAN score — 85.9% of patients had sub-coil adipose tissue thickness of ≤ 1 coil width — the lowest coil to sternum measurement possible for this step in the PRAETORIAN score.¹² Low voltage impedance measurements may also serve as an evaluation of sub-coil adipose tissue during the procedure.¹² The registry found there was a 98% likelihood (NPV) that the PRAETORIAN score is < 90 with a shock impedance of $\leq 88\Omega$.¹²

Minimizing adipose tissue under the coil and pulse generator is a key component of achieving a low PRAETORIAN score.³

*The manufacturer recommended VF conversion testing during EMBLEM S-ICD implant and replacement procedures is being evaluated based on the PRAETORIAN DFT trial results and additional available data.

NPV = Negative Predictive Value

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