SUPPLEMENTAL MATERIAL

Supplemental table 1 Baseline characteristics of patients approached for PRAETORIAN-XL

	Included in PRAETORIAN-XL	Not included in PRAETORIAN-XL	
	N=528	**N=121**	**P-value**
Median age (IQR) — yr	63.0 [55.0 - 69.0]	59.0 [51.5 - 68.0]	0.010
Female sex — no. (%)	98 (18.6)	27 (22.3)	0.345
Diagnosis — no. (%)			0.513
Ischemic cardiomyopathy	362 (68.6)	85 (70.2)	
Nonischemic cardiomyopathy	117 (22.2)	31 (25.6)	
Genetic arrhythmia syndrome	31 (5.9)	3 (2.5)	
Congenital heart disease	4 (0.8)	1 (0.8)	
Idiopathic VF	11 (2.1)	1 (0.8)	
Other	3 (0.6)	0 (0.0)	
Secondary prevention — no. (%)	115 (21.8)	14 (11.6)	0.011
Median ejection fraction (IQR) — %	30.00 [25.0 - 35.0]	30.00 [25.0 - 34.0]	0.220
Mean QRS duration ± SD — ms	104.6 (18.5)	102.4 (21.8)	0.247
NYHA class — no./total no. (%)			<0.001
I	205/526 (39.0)	25/121 (20.7)	
II	268/526 (51.0)	66/121 (54.5)	
III/IV	53/526 (10.1)	30/121 (24.8)	
Median body-mass index (IQR)	27.5 [25.0 - 31.2]	28.1 [25.6 - 31.2]	0.120
Hypertension or antihypertensive drugs — no./total no. (%)	283/525 (53.9)	69/120 (57.5)	0.475
Hypercholesterolemia or lipid-lowering drugs — no./total no. (%)	200/524 (38.2)	61/118 (51.7)	0.007
Current or recent smoker — no./total no. (%)	151/506 (29.8)	45/113 (39.8)	0.039
Diabetes mellitus — no./total no. (%)	131/527 (24.9)	41/121 (33.9)	0.043
Previous CABG — no./total no. (%)	96/525 (18.3)	23/121 (19.0)	0.853
History of atrial fibrillation — no./total no. (%)	124/526 (23.6)	25/121 (20.7)	0.493
History of nonsustained VT — no./total no. (%)	52/525 (9.9)	7/120 (5.8)	0.163
History of syncope — no./total no. (%)	34/523 (6.5)	10/120 (8.3)	0.473

CABG=coronary artery bypass graft; IQR=interquartile range; NYHA=New York Heart Association; SD=standard deviation; VF=ventricular fibrillation; VT=ventricular tachycardia.

Supplemental table 2 Baseline characteristics of patients who consented for PRAETORIAN XL

	S-ICD	TV-ICD	p-value
	N=263	**N=265**	
Median age (IQR) — yr	62.0 [55.0 - 69.0]	64.0 [55.0 - 68.0]	0.382
Female sex — no. (%)	47 (17.9)	51 (19.2)	0.685
Diagnosis — no. (%)			0.352
Ischemic cardiomyopathy	179 (68.1)	183 (69.1)	
Nonischemic cardiomyopathy	56 (21.3)	61 (23.0)	
Genetic arrhythmia syndrome	15 (5.7)	16 (6.0)	
Congenital heart disease	2 (0.8)	2 (0.8)	
Idiopathic VF	8 (3.0)	3 (1.1)	
Other	3 (1.1)	0 (0.0)	
Secondary prevention — no. (%)	56 (21.3)	59 (22.3)	0.787
Median ejection fraction (IQR) — %	30.0 [25.0 - 35.0]	30.0 [25.0 - 35.0]	0.739
Mean QRS duration ± SD — ms	105.5 (18.2)	103.7 (18.8)	0.269
NYHA class — no./total no. (%)			0.514
I	108/262 (41.2)	97/264 (36.7)	
II	127/262 (48.5)	141/264 (53.4)	
III/IV	27/262 (10.3)	26/264 (9.8)	
Median body-mass index (IQR)	26.9 [24.7 - 30.6]	28.1 [25.4 - 31.7]	0.020
Hypertension or antihypertensive drugs — no./total no. (%)	133/262 (50.8)	150/263 (57.0)	0.150
Hypercholesterolemia or lipid-lowering drugs — no./total no. (%)	93/261 (35.6)	107/263 (40.7)	0.234
Current or recent smoker — no./total no. (%)	65/252 (25.8)	86/254 (33.9)	0.052
Diabetes mellitus — no./total no. (%)	57/263 (21.7)	74/264 (28.0)	0.091
Previous CABG — no./total no. (%)	49/262 (18.7)	47/263 (17.9)	0.805
History of atrial fibrillation — no./total no. (%)	71/263 (27.0)	53/263 (20.2)	0.064
History of nonsustained VT — no./total no. (%)	26/262 (9.9)	26/263 (9.9)	0.988
History of syncope — no./total no. (%)	11/260 (4.2)	23/263 (8.7)	0.050

CABG=coronary artery bypass graft; IQR=interquartile range; NYHA=New York Heart Association; SD=standard deviation; VF=ventricular fibrillation; VT=ventricular tachycardia.

Supplemental table 3 Total of major complications

	S-ICD	TV-ICD
Total major complications	**30**	**48**
Infection	5	9
Bleeding	2	1
Thrombotic event	0	0
Pneumothorax	0	2
Lead perforation	0	1
Tamponade	0	2
Lead repositioning	3	7
Lead dislocation	2	5
Lead dysfunction	0	2
DFT failure	1	0
Other lead or device complications	20	26
Lead replacement	6	14
Lead dysfunction	2	8
Lead dislocation	2	3
Lead fracture	1	3
Inappropriate therapy	1	0
Sensing issues	7	1
Device malfunction	1	3
DFT failure	3	0
Implantation failure	0	3
Pain or discomfort	2	5
Other*	1	0

DFT=defibrillation test; S-ICD=subcutaneous implantable cardioverter-defibrillator; TV-ICD=transvenous implantable cardioverter-defibrillator.

**This was an hemothorax after a CRT-D implantation and S-ICD extraction.*

Supplemental table 4 Complications and the type of device it occurred in

	S-ICD	TV-ICD	CRT-D
Total Device-related complications	**33**	**58**	**7**
Infection	4	9	1
Bleeding	9	3	0
Thrombotic event	1	2	0
Pneumothorax	0	4	0
Lead perforation	0	2	0
Tamponade	0	1	1
Lead repositioning	2	7	1
Lead dislocation	1	5	1
Lead dysfunction	0	2	0
DFT failure	1	0	0
Other lead or device complications	17	30	4
Lead replacement	3	14	3
Lead dysfunction	0	8	2
Lead dislocation	1	3	1
Lead fracture	1	3	0
Inappropriate therapy	1	0	0
Sensing issues	7	3	0
Device malfunction	1	4	0
DFT failure	4	0	0
Implantation failure	0	3	0
Pain or discomfort	2	6	0
Other*	0	0	1

DFT=defibrillation test; S-ICD=subcutaneous implantable cardioverter-defibrillator; TV-ICD=transvenous implantable cardioverter-defibrillator.

**This was an hemothorax after a CRT-D implantation and S-ICD extraction.*

Supplemental table 5 Generator changes for battery depletion

	S-ICD	TV-ICD
Total number of generator changes	199†	39‡
Early battery depletion	49*	8*
Normal battery depletion	151	32

To be defined as early battery depletion, a generator change had to be reported by site AND reported as Advisory by Boston Scientific AND reported in the source document.

S-ICD=subcutaneous implantable cardioverter-defibrillator; TV-ICD=transvenous implantable cardioverter-defibrillator.

**One patient in the S-ICD arm and one patient in the TV-ICD arm had early battery depletion in whom instead of a battery change the device was extracted. This was an S-ICD in both arms.*

†This includes one generator change in a CRT-D instead of S-ICD and one generator change in a TV-ICD.

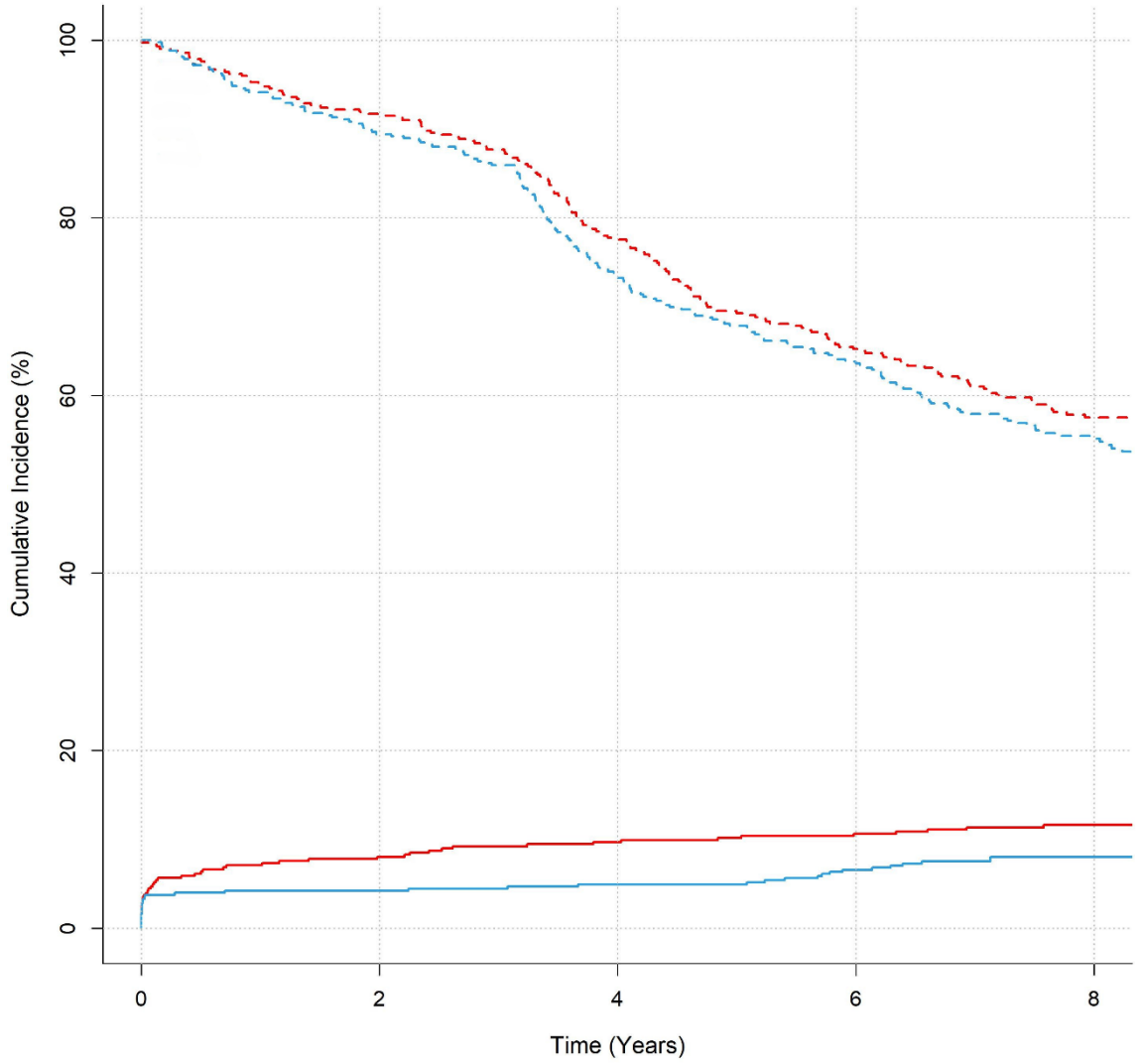
‡This includes three generator changes in an S-ICD instead of TV-ICD.

Supplemental table 6 Causes of death

Cause of death	S-ICD (N=125)	TV-ICD (N=123)
Sudden cardiac death	**23**	**27**
Cardiac arrest or cardiogenic shock	8	8
Unexplained (sudden) death	15	19
Other cardiovascular death	**48**	**49**
End-stage heart failure	35	36
Vascular disease (including stroke)	5	8
Miscellaneous	8	5
Non-cardiovascular death	**54**	**47**
Carcinoma	25	17
Infection or sepsis	13	17
Gastrointestinal disease	7	3
Pulmonary disease	4	6
Neuropsychiatric disease	3	1
Miscellaneous	2	3

S-ICD=subcutaneous implantable cardioverter-defibrillator; TV-ICD=transvenous implantable cardioverter-defibrillator.

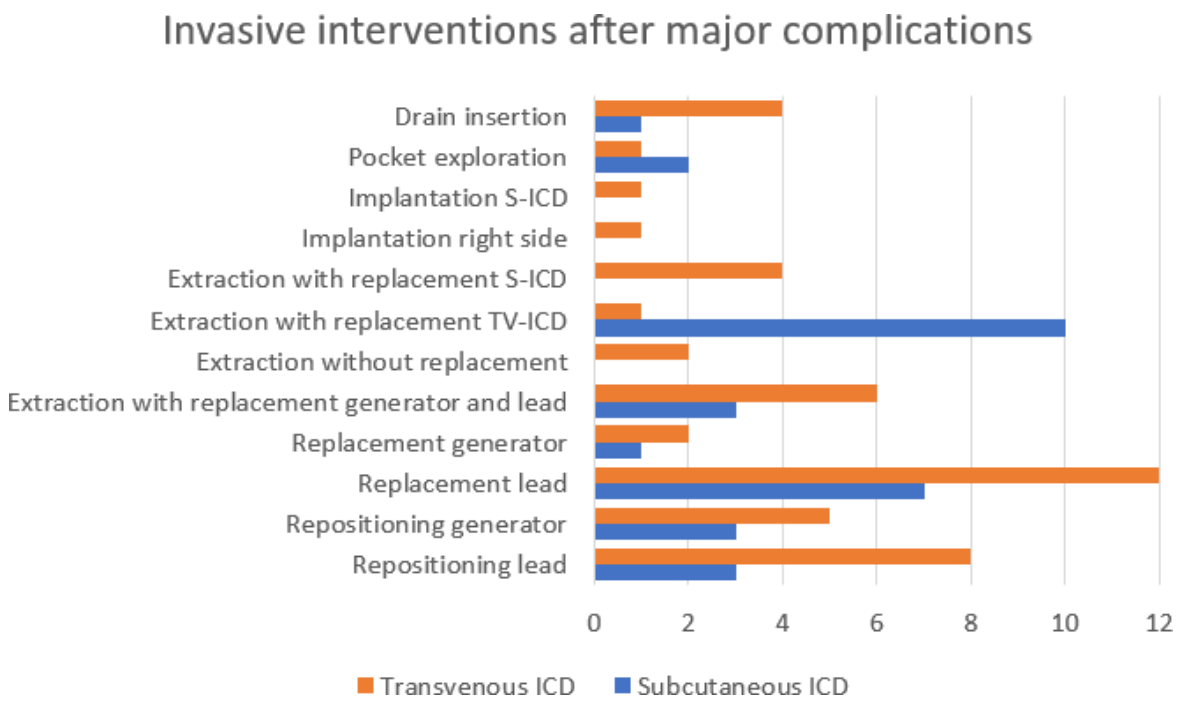
Supplemental figure 1 Cumulative incidence curves of alle device-related complications including the curves for the competing risk of death and loss to follow-up



The dotted lines indicate the cumulative incidences of study dropout due to death or loss to follow-up. The straight lines indicate the cumulative incidences of the primary endpoint of all device-related complications. Red=TV-ICD; Blue=S-ICD.

The figure shows that patient loss was comparable between study arms.

Supplemental figure 2 Invasive interventions following a major complication



S-ICD=subcutaneous implantable cardioverter-defibrillator; TV-ICD=transvenous implantable cardioverter-defibrillator.

In one patient, the cephalic and subclavian vein on the left side could not be identified. The ICD generator was therefore implanted on the right side.

One patient deceased as a result of the major complication and no invasive intervention was therefore performed.

Additional statistical considerations and analyses

The PRAETORIAN-XL study has a very long follow-up duration resulting in a large proportion of patients not completing full follow-up due to death or dropout before study completion. Therefore, a Fine-Gray subdistribution hazard model with mortality and patient loss to follow-up as competing risk was used as primary statistical model. There were comparable rates of loss to follow-up and mortality in both arms, as illustrated in Supplementary Figure 1. The proportional hazard assumption was assessed by comparing the log(-log(1-CIF)) plots of cumulative hazards between the treatment groups. The proportional hazard assumption was violated in the modified intention-to-treat analysis for all complications as well as major and lead-related complications. A landmark analysis demonstrated that the proportional hazard assumption was not violated at a follow-up duration of 48 months (Knops et al. Eur Heart J. 2022 Dec 14;43(47):4872-4883). Therefore, the violation of proportional hazards occurred after 48 months, which aligns with the break in the estimated cumulative incidence curve in the S-ICD group at 48 months. The effect sizes reported should therefore be interpreted as overall risk after 8 years and not as a constant hazard. For the as-treated analysis, in which a time-dependent Cox proportional hazards model was used, the proportional hazard check showed no violation of the proportional hazard.

At last, in all models presented in the main paper, randomization group was the covariate used. Other variables were not included in these analyses. A sensitivity analysis correcting the models for variables age (≥65 and <65 years), sex, BMI (≥25and <25 kg/m2), atrial fibrillation, diabetes, and smoking showed comparable results for all analyses.

Appendix – List of PRAETORIAN-XL investigators

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