

TCT 2025
SOLO-TAVR

SOLOPACE™

Single One wire Logistics Optimizes Transcatheter Aortic Valve Replacement

First In human experience with a new dedicated complete system for TAVR pacing

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TRANSCATHETER
CARDIOVASCULAR
THERAPEUTICS®



Waikato District Health Board

Disclosure of Relevant Financial Relationships

I, Dr Sanjeevan Pasupati, DO NOT have any financial relationships to disclose.



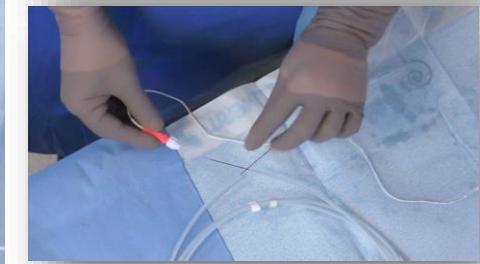
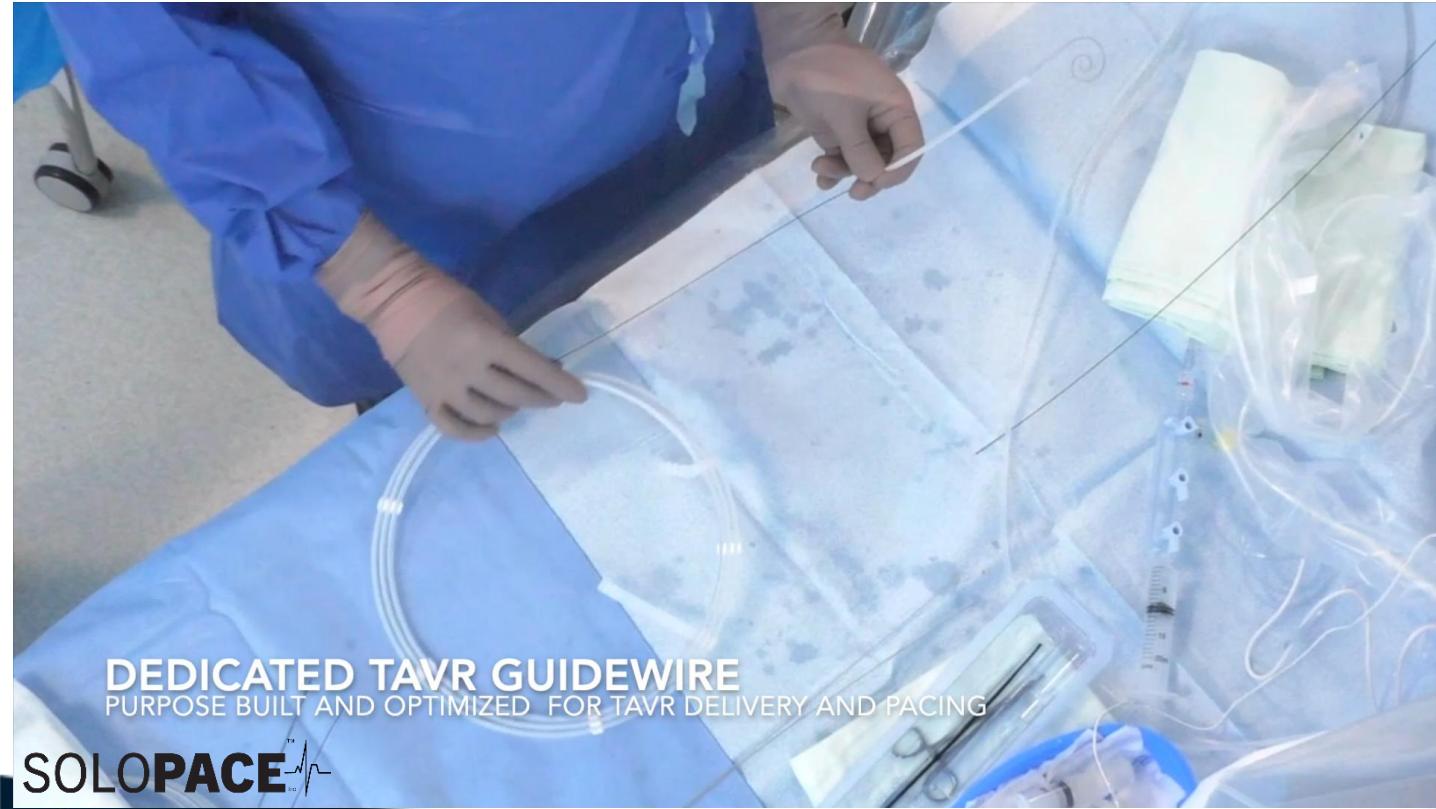
Background



- First in its class, with a complete TAVR pacing system
- Combination of purpose-built *Pace Generator* with advanced TAVR specific pacing algorithms + sterile *Remote*
- Complete LV pacing kit with pre shaped guidewire optimized for *Pacing AND Performance*

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Fusion PACE wire

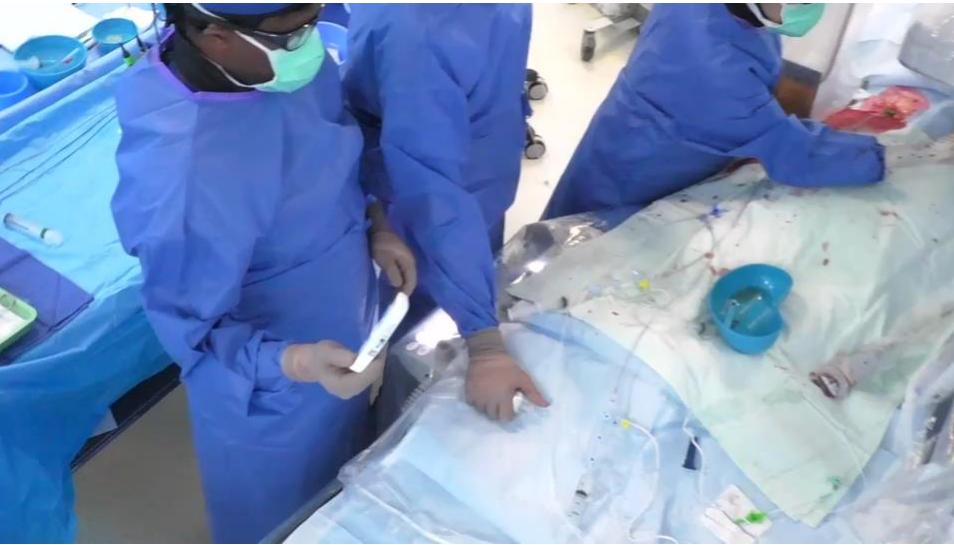


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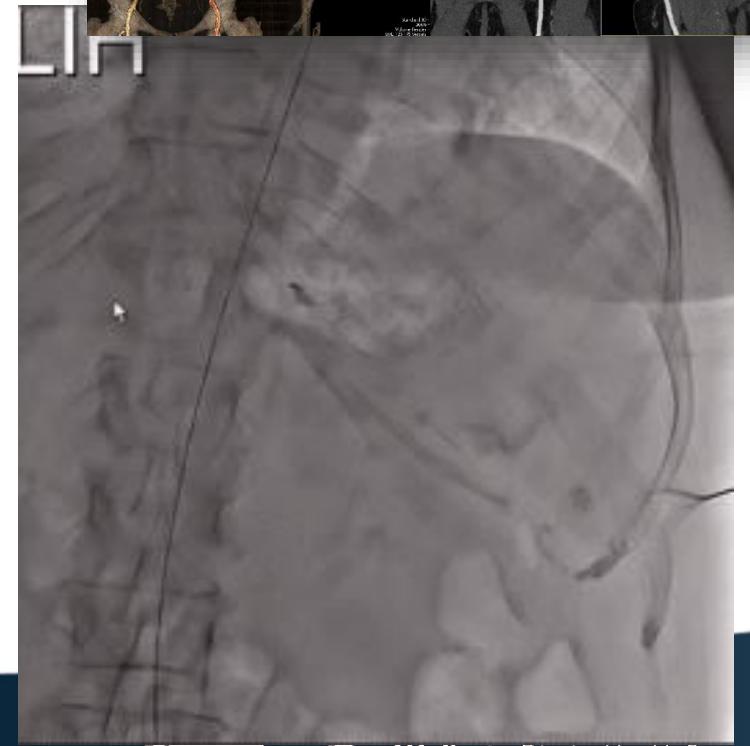
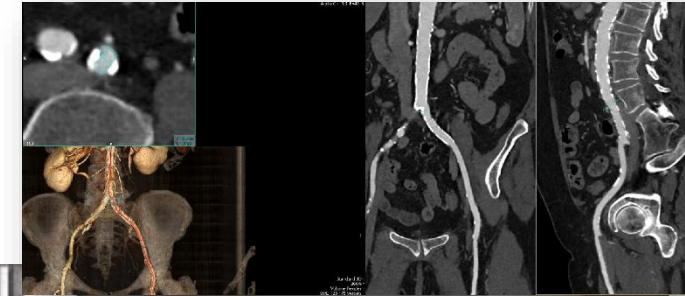
Case Presentation

- 80-year-old with severe aortic stenosis
- PMHx: Hypertension, Renal Calculi
- TTE: APG 83mmHg, AMG 55mmHg, AVA 0.67cm^2 , AR2+, MR1+, EF58%
- Mild CAD
- CT: Non-Hostile Aortic annulus (Area 435cm^2), Suitable for low-risk TF TAVI, moderately calcified femoral vessels.

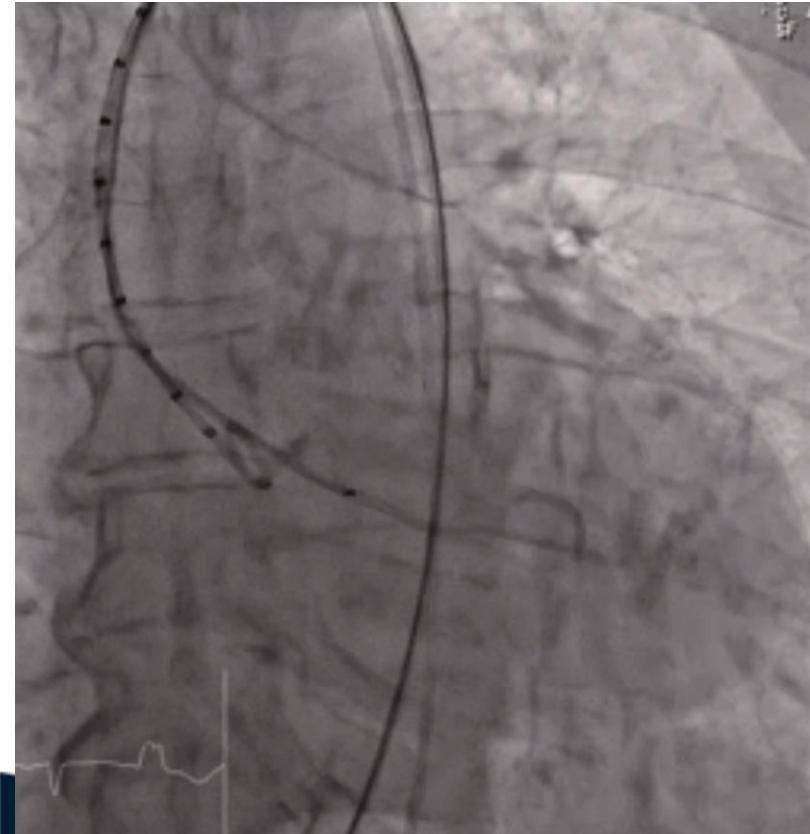




Single wire for Valve delivery and sheath advancement



Maintenance of wire shape



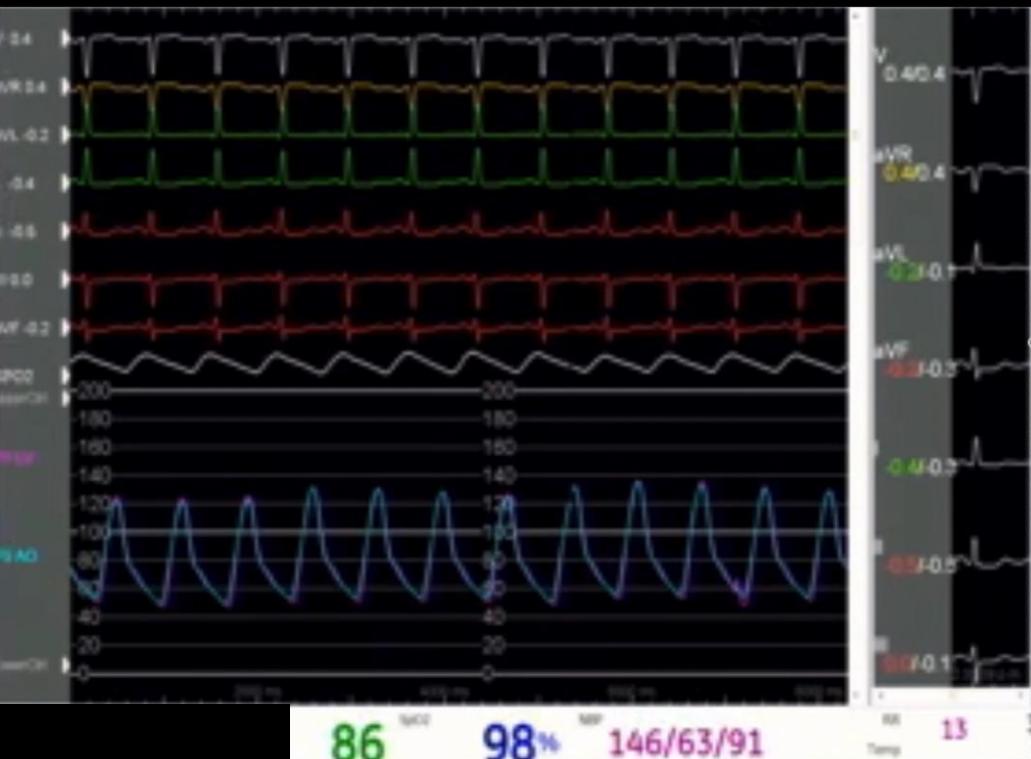
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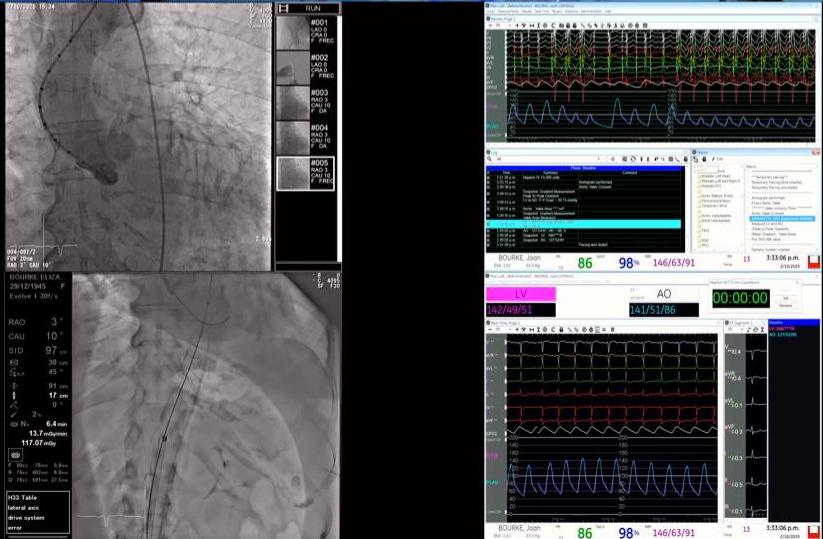


Capture Check - Fusion wire



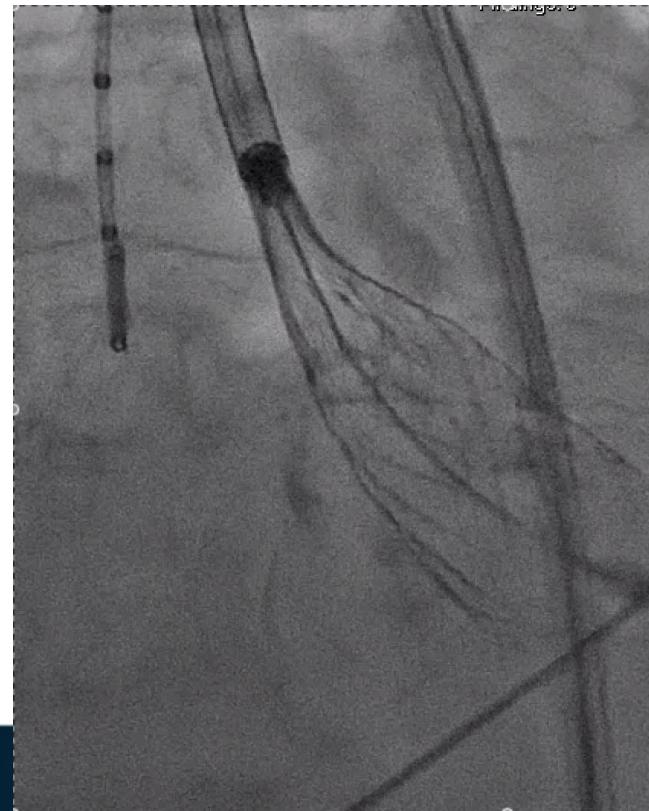
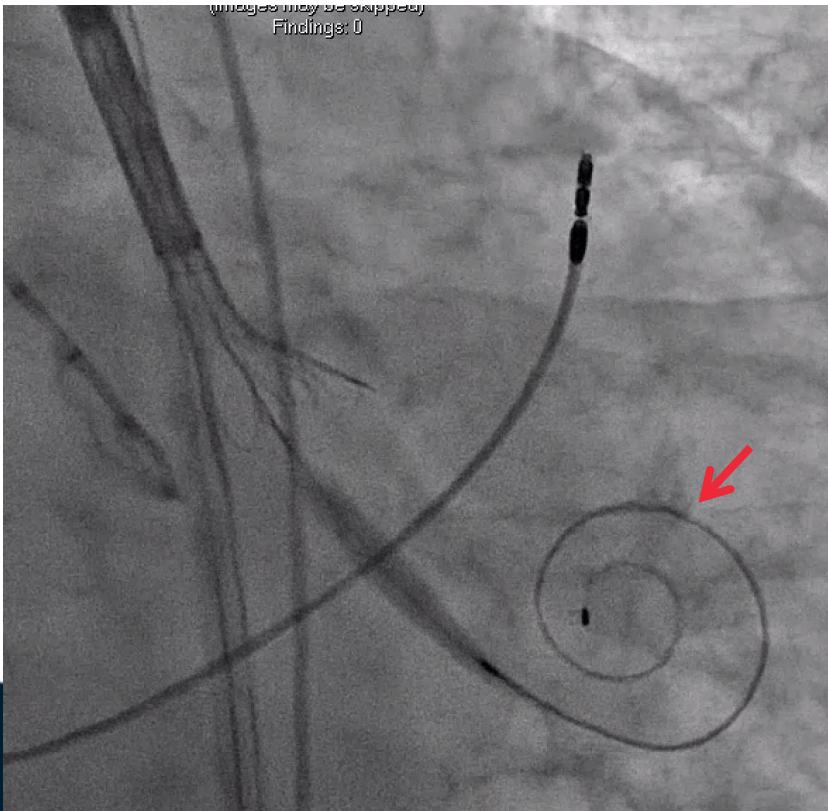
86 98% 146/63/91

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Delivery and Pacing With Deployment

Self-expanding valve deployment and release



FIH Trial Design

- Single-arm prospective registry
- 10 patients enrolled at a single centre (Waikato DHB) in New Zealand
- Undergoing TAVR or BAV
- **Primary endpoint:** Successful delivery AND successful pacing over the Fusion Guidewire
- **Primary safety endpoint:** Failure of the Fusion System to provide adequate pacing leading to valve migration/embolization

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Outcomes

- Procedural success: 100% (10/10) — Stable capture and Successful TAVR
- Device-related adverse events: 0 / 10 (0%) — No pacing system malfunction or performance issues
- Permanent pacemaker implantation: None required — All patients maintained intrinsic conduction
- Valves implanted: Evolut FX+ (6), Sapien 3UR (3), BAV Balloon (1)

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SOLO-TAVR Summary Table

Patient	Age	Sex	STS	NYHA	LVEF	Conduction Disorder	Conduction Type	Valve Device	Success	Time (min)	AE	AE Type
1	77.0	M	2.03	2.0	55.0	No	-	Evolut FX	Y	65.0	Y	TIA
2	78.0	F	2.54	3.0	45.0	No	-	Evolut FX	Y	60.0	N	-
3	93.0	F	11.6	2.0	55.0	Yes	LBBB	BAV Balloon	Y	104.0	N	-
4	77.0	F	4.08	2.0	45.0	Yes	AF	Evolut FX	Y	54.0	Y	Bradycardia
5	79.0	F	2.4	2.0	55.0	No	-	Sapien 3	Y	50.0	Y	Arterial dissection and fever
6	77.0	M	7.0	2.0	40.0	Yes	RBBB+LAFB	Sapien 3	Y	63.0	Y	New onset AF
7	88.0	M	6.0	2.0	45.0	Yes	AF	Evolut FX	Y	94.0	N	-
8	87.0	F	6.0	2.0	45.0	No	-	Evolut FX	Y	69.0	N	-
9	83.0	M	7.0	3.0	45.0	Yes	AF	Evolut FX	Y	69.0	N	-
10	74.0	M	2.0	3.0	60.0	No	-	Sapien 3	Y	53.0	Y	Fever, self limited, no sequalae

Conclusions

- We report the FIH experience of the **SOLO PACE** Fusion system
- 100% procedural success with *no* loss of capture
- First of its kind, fully integrated kit that includes:
 - Smart pacing generator and controller
 - Complete LV Pacing Kit including a dedicated pre-shaped pacing wire, ground pad and a connector cable

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