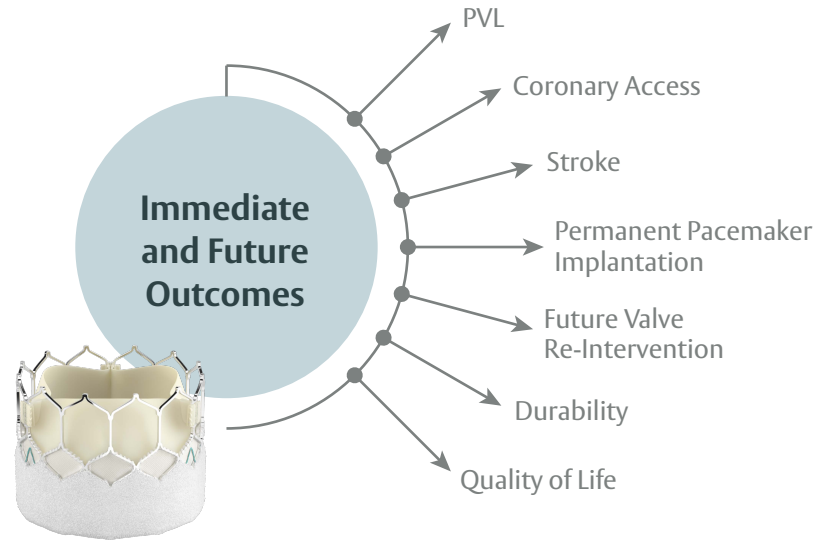


THV-in-THV with the SAPIEN 3 Ultra valve

When choosing the first THV, consider your patient's future

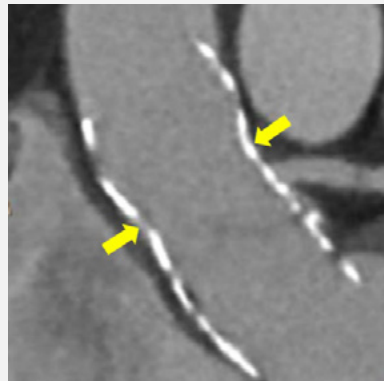


The first THV has a critical impact on patient lifetime management



When implanting the first THV, consider future coronary access feasibility¹⁻³

SAPIEN 3 Ultra valve reduces the risk of impaired coronary access⁴



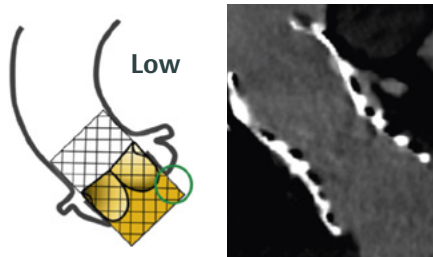
The combination of a high risk plane and low VTA distance might cause critical blockage of sinus

- Risk plane above coronaries
- VTA ≤ 2 mm

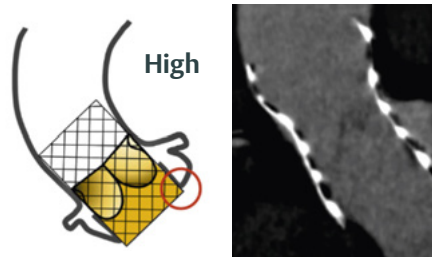
Sinus sequestration is due to commissure/frame overlapping with coronary ostia

When choosing the first THV, consider potential tradeoff between coronary access and new permanent pacemaker implantation rates⁵

Increased Pacemaker Implantation



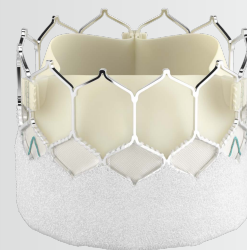
Reduced Coronary Access



SAPIEN 3 Ultra valve minimizes new permanent pacemaker implantation rates and risk of coronary access impairment

SAPIEN 3 Ultra valve is designed for lifetime management

SAPIEN 3 Ultra is the only CE marked valve for THV-in-THV



Outcomes of THV-in-THV with SAPIEN 3 Ultra valve are no different from native TAVI⁶

Adjusted overall cohort		S3 / S3U THV-in-THV n = 591	S3 / S3U Native TAVI n = 591	P Value
30 days	Death	4.9%	4.1%	0.47
	Stroke	2.4%	1.4%	0.19
	New pacemaker w/o baseline	9.9%	9.9%	0.98
	Aortic valve reintervention	0.7%	0.4%	0.41
	Mod/Severe PVL	3.6%	2.6%	0.43
1 year	Death	15.6%	18.6%	0.33
	Stroke	2.4%	2.6%	0.67
	New pacemaker w/o baseline	12.7%	11.3%	0.65
	Aortic valve reintervention	1.9%	0.6%	0.12
	Mod/Severe PVL	1.4%	3.1%	0.47

1. Rogers, T. et al. Feasibility of Coronary Access and Aortic Valve Reintervention in Low-Risk TAVR Patients. JACC. 2020; 13(6): 726-735. / 2. Ochiai, T. et al. Risk of Coronary Obstruction Due to Sinus Sequestration in Redo Transcatheter Aortic Valve Replacement. JACC. 2020;13(22): 2617-2627. / 3. De Backer, O. et al. Coronary access after TAVR-in-TAVR as evaluated by multidetector computed tomography. JACC. 2020;13(21): 2528-2538. / 4. Nai Fovino, L. et al. Coronary Angiography After TAVR to Evaluate the Risk of Coronary Access Impairment After TAVR-in-TAVR. JAHA. 2020; 9:e016446. / 5. Buzzatti, N. et al. Coronary Access After Repeated Transcatheter Aortic Valve Implantation: A Glimpse Into the Future. JACC Cardiovasc Imaging. 2020;13(2 Pt 1):508-515. / 6. Makkar, R. et al. Outcomes of Repeat Transcatheter Aortic Valve Replacement with Balloon-Expandable SAPIEN 3/Ultra Valves. Presented at TCT Orlando 2021.

THV-in-THV = transcatheter heart valve in transcatheter heart valve; PVL = paravalvular leak; VTA = valve to aorta distance; LVOT = left ventricular outflow tract, SoV = sinus of Valsalva; TAVI = transcatheter aortic valve implantation

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