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SAPIEN 3 Ultra — Design and procedural features of a new balloon-expandable valve

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Introduction

Balloon-expandable (BE) SAPIEN 3 transcatheter heart valves (Edwards Lifesciences, Irvine, CA, USA) have a track record of excellent deliverability, low risk of paravalvular regurgitation (PVL), permanent pacemaker implantation and incidence of stroke. This technology evolved into the current version by reduction of the delivery profile achieved by alignment of the valve on the balloon in the descending aorta, improvement of sealing by the outer PET skirt and use of an expandable, hydrophilic-coated femoral sheath. In February 2019 a new system — SAPIEN 3 Ultra was launched in Poland. It has important new features which warrant discussion: 1) higher outer skirt with redesigned structure, 2) delivery system (low profile nosecone, on-balloon valve crimping, dual articulation), and 3) expandable, seamless delivery sheath. The valve CoCr stent, bovine pericardial leaflets, and inner sealing skirt remain unchanged.

The main goals for the design improvements are simplification of the procedure, further reduction of PVL risk and a decrease in vascular complications [1].

The redesigned outer sealing skirt

Results of the PARTNER trials showed a very low risk of PVL, in particular when using the 29 mm valve with a higher outer sealing skirt than smaller sized valves [2–4]. It has led to an increase in height of the sealing skirt by 40% in S3 Ultra vValves resulting in a 50% increase of the area of contact with the native anatomy. The sealing PET skirt has a textured

structure which promotes healing and endothelialization. The external skirt design is introduced in 20, 23 and 26 mm S3 Ultra valves while the 29 mm valve remains the current S3 model.

The delivery system

New features of the S3 Ultra delivery system reduce the number of procedural steps and offers low system profiles across all valve sizes. The S3 Ultra valve is crimped directly on the balloon, so there is no need to align it in the descending aorta or to retract the flex catheter before implantation. Also, the distal tip of the balloon was redesigned: it has a short, tapered tip with a smooth transition to the valve and lower crossing profile. The delivery catheter has controlled dual articulation which allows avoiding contact with the aortic walls during crossing of the arch.

The delivery sheath

The Axela sheath is an expandable, and self-collapsible 14 F system with a hydrophilic coating. The expansion of the sheath is transient and has an outer elastomeric jacket which forces active contraction of the sheath walls after valve passage. The 14 F sheath is compatible with all valve sizes. It has a seamless design to reduce the risk of bleeding or vessel trauma during the procedure.

For the transapical approach, the Certitude delivery system allows the use of S3 Ultra valves with 18 F sheaths for 20 mm or 21 F sheaths for 23–29 mm valves.

Procedural remarks

The recommendations for valve sizing based on the angio-computed tomography remains the same as for S3. The differences during the procedure are mainly related to tracking and positioning of the new delivery system and valve. Since there is no need for valve alignment after passing in the descending aorta, the delivery system can be flexed earlier than in the S3 system valve to avoid contact with the aortic wall. The S3 Ultra can be positioned for implantation directly after crossing of the native valve. It is recommended to push the valve into the left ventricle slightly lower than the intended level of implantation, then withdraw it and by using the distal handle knob to fine-tune the optimal position. Also, it is suggested to place the radiopaque marker 1–2 mm higher above the annular plane than for the S3 valve. Importantly, the expansion of the newly designed balloon starts at the proximal (aortic) end, unlike in the S3 system. Therefore, it is not possible with S3 Ultra to use a small

amount of contrast to dilate the distal end of the balloon to facilitate the direct implantation in case of difficult crossing of a calcified native valve. Finally, the balloon should be fully emptied from contrast before withdrawal into the Axela sheath.

The initial experience of five procedures using the S3 Ultra in patients with severe stenosis of tricuspid, and bicuspid native aortic valves and for valve-in-valve implantation showed easy access site handling, good trackability and procedural results with no PVL.

Conflict of interest: Radosław Parma, Wojciech Wojakowski — Lecture honoraria: Edwards Lifesciences.

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Figure 1. The SAPIEN 3 Ultra system; **A.** S3 Ultra valve with a redesigned outer skirt (1); **B.** Balloon and crimped valve; **C.** Delivery system; **D.** Axela sheath with cross-section showing outer elastomeric jacket and folded expandable wall of the inner sheath. Modified from images provided by Edwards Lifesciences with written permission to use in print.

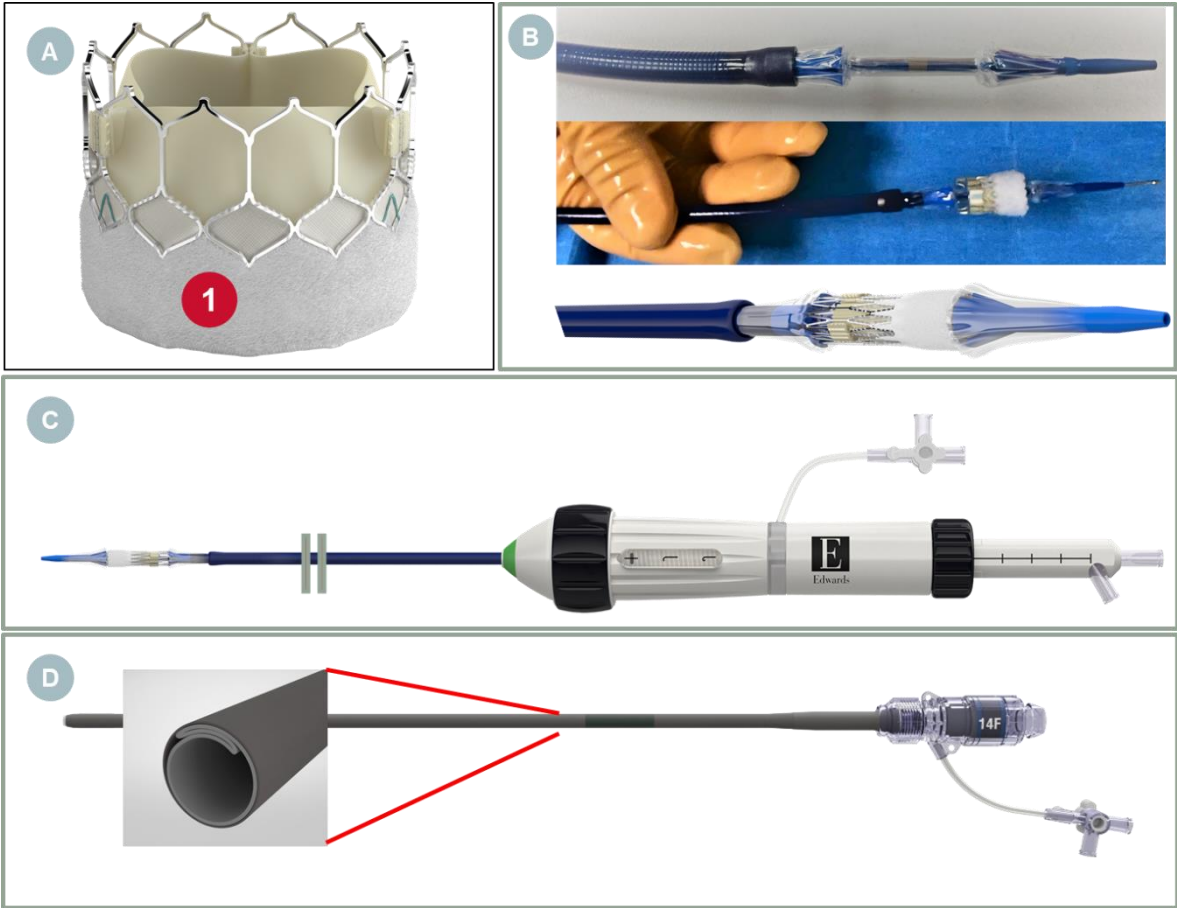


Figure 2. The SAPIEN 3 Ultra implantation; 1 — The fluoroscopic appearance of the flex catheter without retractable pusher; 2 — Inflation of the balloon starting at its proximal end.

