PORTICO™ TAVI SYSTEM

CLINICAL PERFORMANCE

HIGHLIGHTS

- Portico Valve with the FlexNav Delivery System is proven to deliver excellent safety outcomes, consistent with leading commercial valves in a high- or extreme-risk patient population[1,2]
- Echo Core Lab data reveals excellent hemodynamic outcomes[1,2]
- PORTICO I real-world study data highlights outcomes comparable to leading TAVI valves[3-8]

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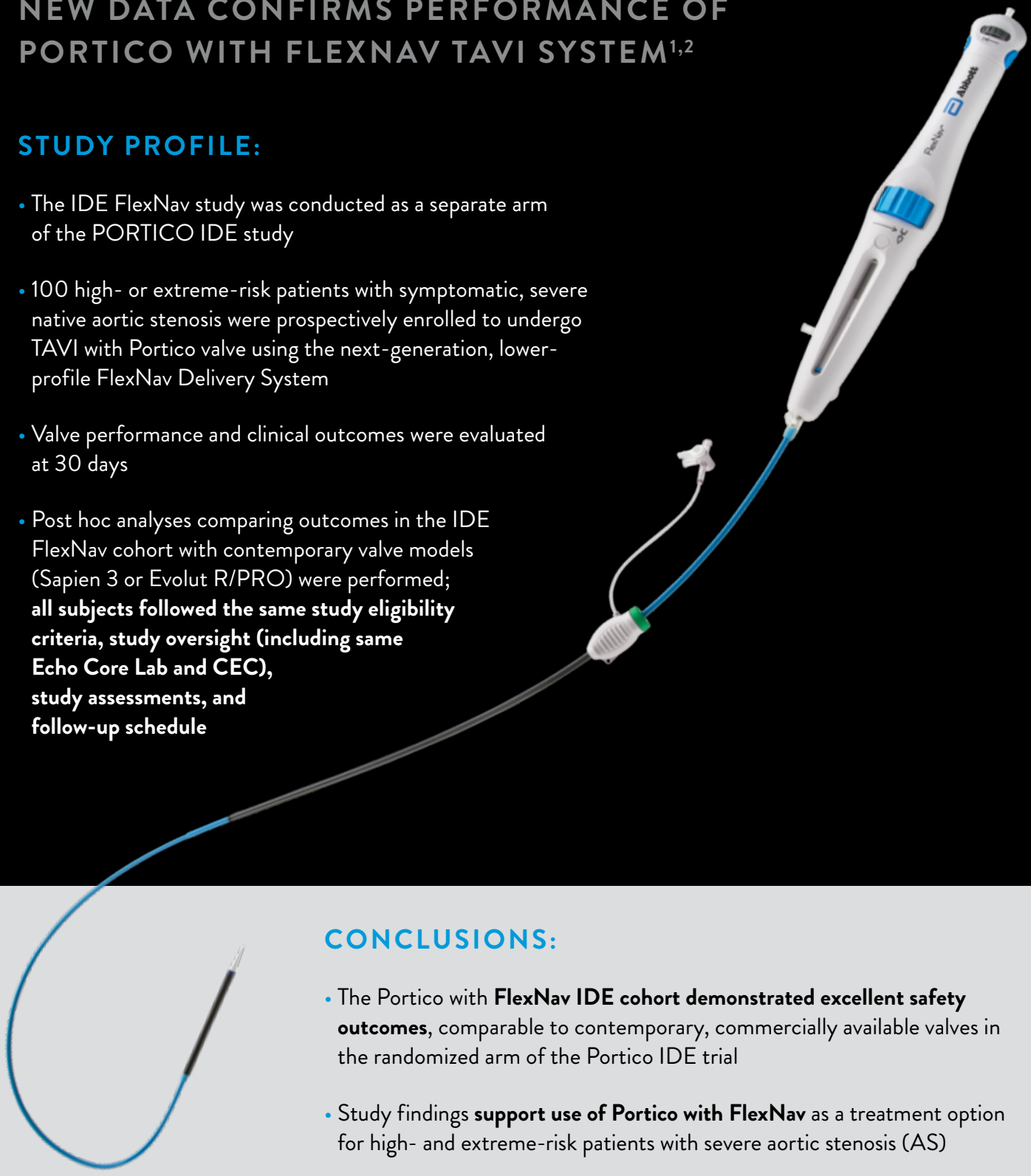
PORTICO WITH FLEXNAV TAVI SYSTEM

NEW DATA CONFIRMS PERFORMANCE OF PORTICO WITH FLEXNAV TAVI SYSTEM[1,2]

STUDY PROFILE:

- The IDE FlexNav study was conducted as a separate arm of the PORTICO IDE study
- 100 high- or extreme-risk patients with symptomatic, severe native aortic stenosis were prospectively enrolled to undergo TAVI with Portico valve using the next-generation, lower-profile FlexNav Delivery System
- Valve performance and clinical outcomes were evaluated at 30 days
- Post hoc analyses comparing outcomes in the IDE FlexNav cohort with contemporary valve models (Sapien 3 or Evolut R/PRO) were performed; **all subjects followed the same study eligibility criteria, study oversight (including same Echo Core Lab and CEC), study assessments, and follow-up schedule**



CONCLUSIONS:

- The Portico with **FlexNav IDE cohort demonstrated excellent safety outcomes**, comparable to contemporary, commercially available valves in the randomized arm of the Portico IDE trial
- Study findings **support use of Portico with FlexNav** as a treatment option for high- and extreme-risk patients with severe aortic stenosis (AS)

PORTICO IDE FLEXNAV COHORT

THE FLEXNAV DELIVERY SYSTEM COHORT OF THE PORTICO IDE STUDY DEMONSTRATED THE FOLLOWING OUTSTANDING OUTCOMES[1,2]:

0% ALL-CAUSE MORTALITY

0% DISABLING STROKE

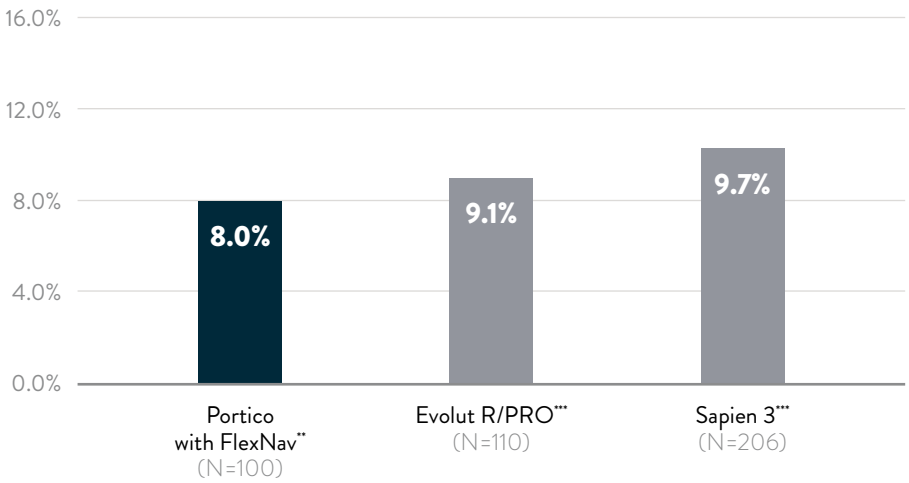
0% AKI III

4% LIFE-THREATENING BLEEDING REQUIRING TRANSFUSION

7% MAJOR VASCULAR COMPLICATIONS*

SAFETY EVENT RATE (30 DAYS)

Composite of all-cause mortality, disabling stroke, life-threatening bleeding requiring blood transfusion, acute kidney injury requiring dialysis, or major vascular complications.



ADVANCING SAFETY WITH FLEXNAV

- Safety benchmarks with use of the next-generation FlexNav Delivery System compared favorably to Sapien 3 and Evolut R/PRO

* 4% TAVI delivery system access-site related complications

** Data represents a non-randomized sample of high or extreme risk patients transfemorally implanted with a Portico valve using the FlexNav Delivery System between November 2018 and June 2019.

*** Data represents a subset of high- or extreme-risk patients implanted with an Evolut R, Evolut PRO, or Sapien 3 valve via a transfemoral or alternative access approach between September 2014 and October 2017. Patients were enrolled as part of a separate pivotal randomized study arm of the PORTICO IDE trial.

CLINICAL OUTCOMES IN CONTEXT

OUTCOMES WITH THE LATEST-GENERATION FLEXNAV DELIVERY SYSTEM ARE CONSISTENT WITH LEADING TAVI VALVES[1,2]

	30-DAY COMPARISON		
	PORTICO WITH FLEXNAV (N=100)*	EVOLUT R/PRO (N=110)**	SAPIEN 3 (N=206)**
All-Cause Mortality (%)	0	0.9	0
Disabling Stroke (%)	0	0.9	1.0
Life-Threatening Bleeding Requiring Transfusion (%)	4.0	4.5	3.4
Major Vascular Complications (%)	7.0	6.4	7.3
New Permanent Pacemaker (%)	14.6	18.9	5.4
AKI III (%)	0	0.9	0
Mean Gradient (mmHg)	6.7	7.3	11.8
Aortic Valve Area (cm^2)	1.8	1.9	1.6
Moderate or Greater PVL (%)	6.5	4.0	1.6

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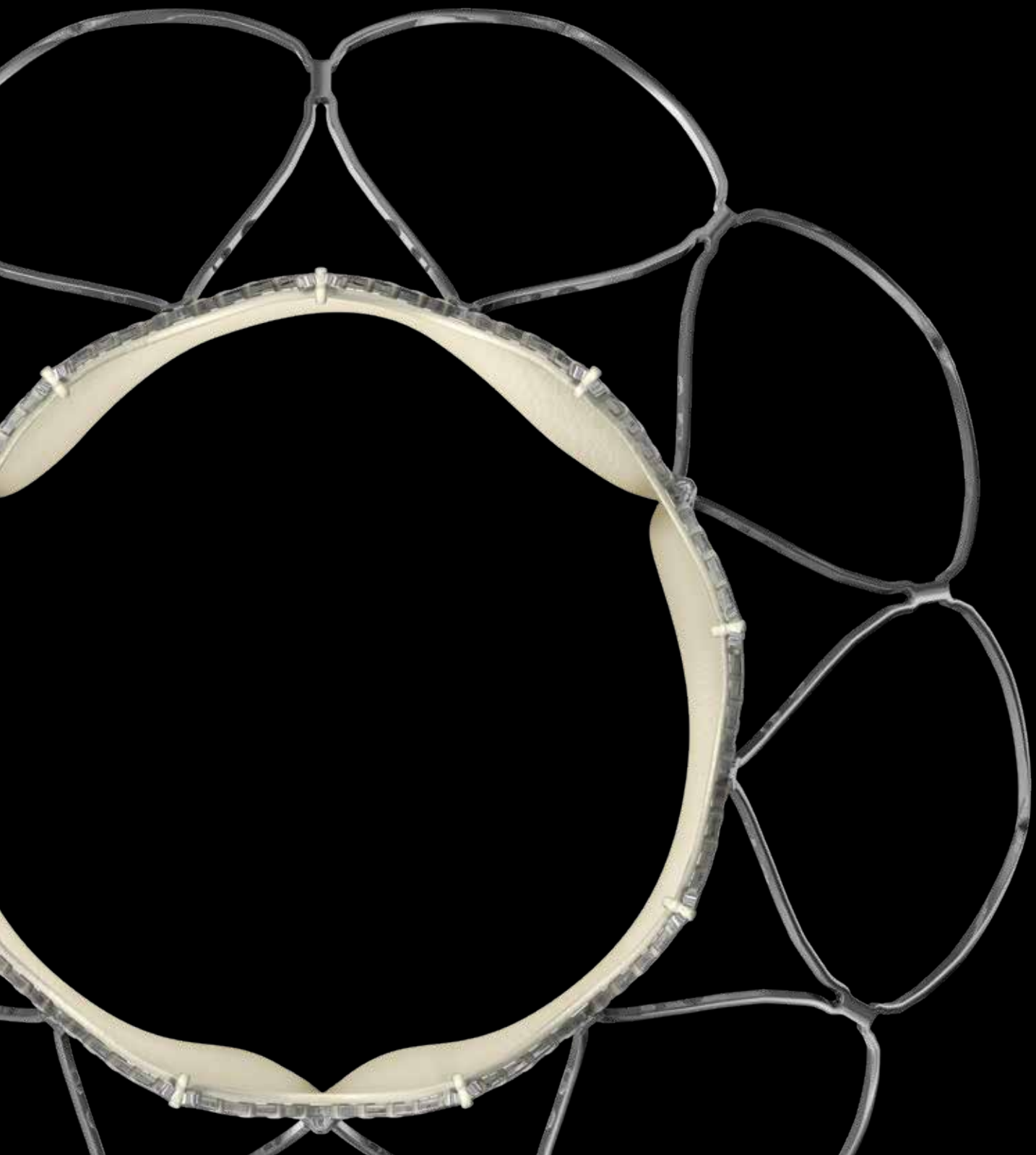
THE ADVANTAGE OF EXPERIENCE

The IDE FlexNav cohort reflects early experience (on average, less than 5 implants) with FlexNav. The PORTICO I Post-Market Clinical Follow-Up Study demonstrates real-world PVL performance of the Portico valve comparable with other leading commercially available valves.

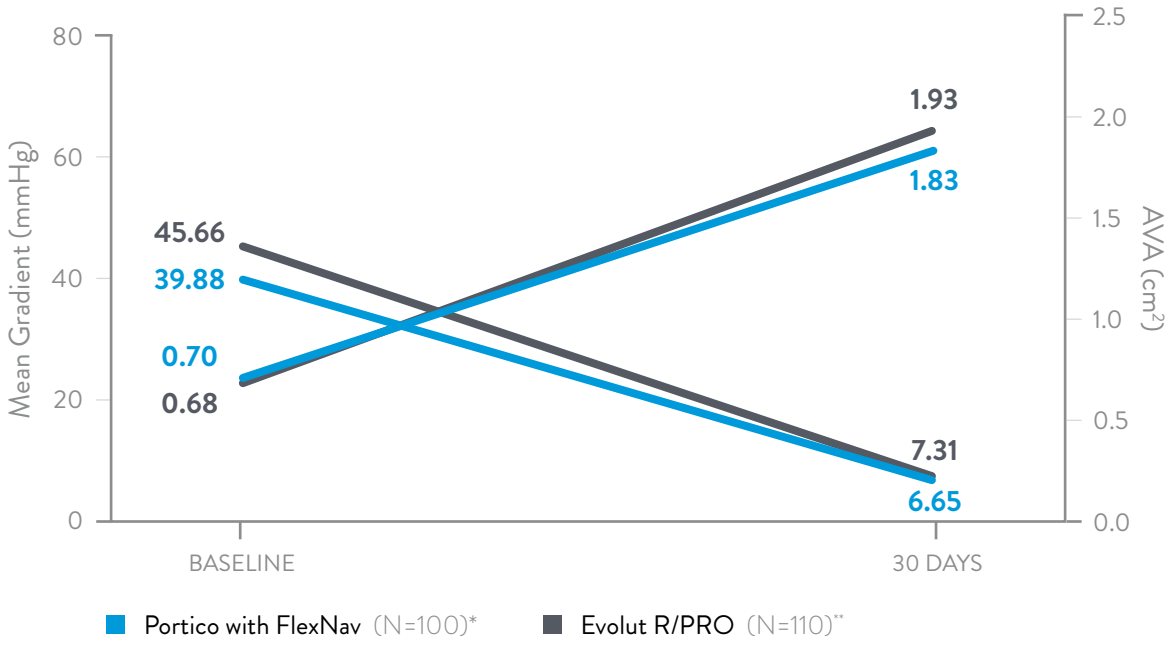
THE HEMODYNAMIC EDGE

Consistent with other leading self-expanding valves, Echo Core Lab data demonstrated that Portico valve outperforms balloon-expandable valves, with single-digit mean gradients and larger AVAs.[1,2]



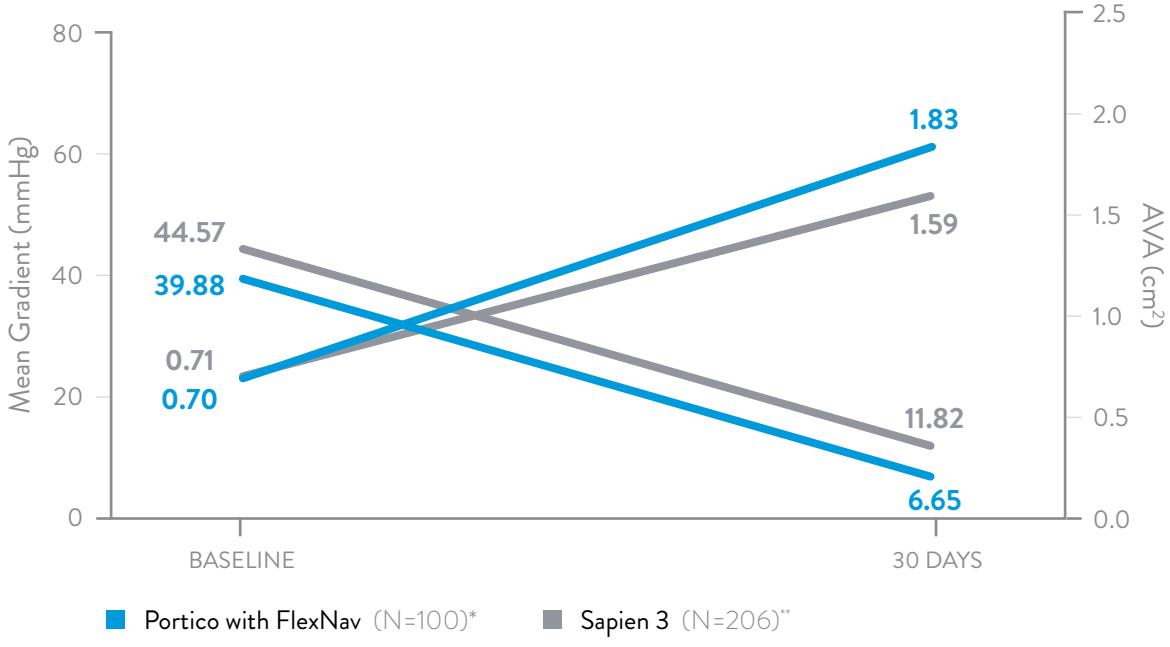
SELF-EXPANDING VALVES. SINGLE-DIGIT GRADIENTS.[1,2]

Intra-annular Portico valve compares favorably to the supra-annular Evolut R/PRO valve.



OUTPERFORMING BALLOON-EXPANDABLE VALVES[1,2]

Intra-annular Portico valve offers excellent hemodynamics compared to intra-annular Sapien 3 valve.



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EXPERIENCE MATTERS

The PORTICO I Post-Market Clinical Follow-up study*, using the previous-generation delivery system, demonstrates excellent short- and long-term clinical outcomes across a broad implanter base, including low rates of PVL, consistent with other leading TAVI valves.[3-8]

	30-DAY COMPARISON		
	PORTICO I[3] **Portico** (N=941)	**FORWARD**[6] **Evolut R** (N=1038)	**SOURCE 3**[7] **Sapien 3** (N=1947)
All-Cause Mortality (%)	2.7	1.9	2.2
Disabling Stroke (%)	1.6	1.7	0.5
Life-Threatening or Disabling Bleeding (%)	3.1	3.7	5.0
Major Vascular Complications (%)	5.5	6.9	4.1
AKI II-III (%)	3	1.1	1.1
New Permanent Pacemaker (%)	18.7	20.2	12.0

IMPLANTER EXPERIENCE IMPACTS PVL

FROM A PORTICO I POST HOC ANALYSIS:

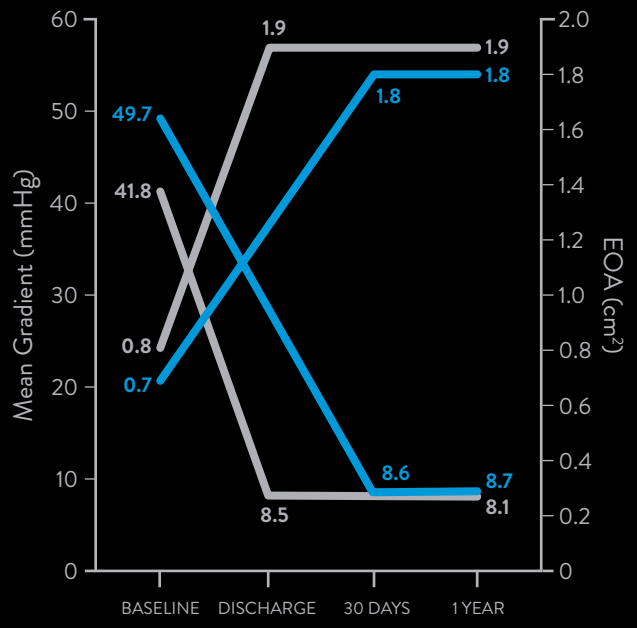
2.6%
PVL

"Sites performing >15 procedures achieved a lower rate of moderate or higher PVL than sites with fewer procedures" (2.6% versus 7.2%, *p*=<0.01, 30-day comparison). —Maisano et. al EuroIntervention 2018

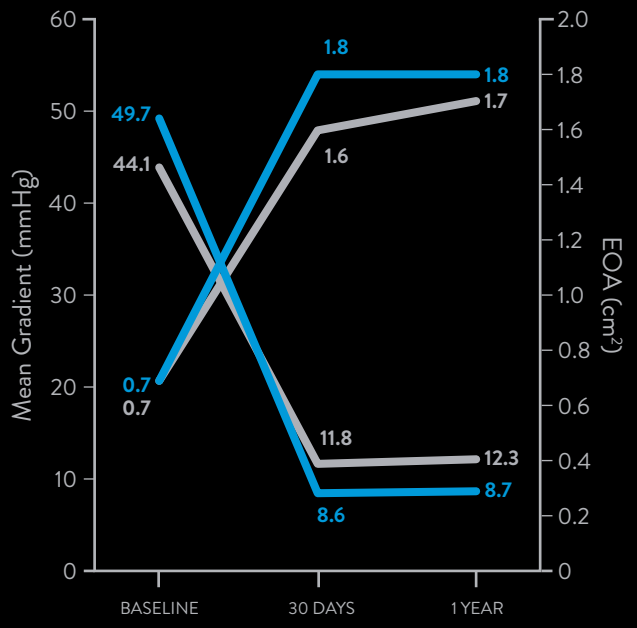
* The Portico I study was conducted via transfemoral access.

EXCELLENT HEMODYNAMIC PERFORMANCE

At 30 days and 1 year, Portico valve demonstrates single-digit mean gradients and large EOAs.[3-8]



■ PORTICO I, Portico (N=941)
■ FORWARD, Evolut R (N=1038)



■ PORTICO I, Portico (N=941)
■ SOURCE 3, Sapien 3 (N=1947)

LOW RATES OF CLINICALLY-SIGNIFICANT PVL

At 30 days and 1 year, Portico valves demonstrate low rates of moderate or higher PVL consistent with other leading TAVI valves.[3-8]

30 DAYS (% ≥ Moderate PVL)

7.2%	2.6%	2.0%*	3.1%
PORTICO I[3,5] **Portico** (N=194) Site ≤ 15 IMPLANTS	**PORTICO I**[3,5] **Portico** (N=495) Site > 15 IMPLANTS	**FORWARD**[6] **Evolut R** (N=813)	**SOURCE 3**[7] **Sapien 3** (N=N/A)

1 YEAR (% ≥ Moderate PVL)

2.6%	1.2%	2.6%
PORTICO I[4] **Portico** (N=573)	**FORWARD**[6] **Evolut R** (N=587)	**SOURCE 3**[8] **Sapien 3** (N=1007)

*at discharge

STUDY OVERVIEWS

PORTICO IDE FLEXNAV COHORT

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BASELINE CHARACTERISTICS

	PORTICO VALVE WITH FLEXNAV (N=100)*
Mean Age	85.2
STS Score (%)	5.0
EuroSCORE II (%)	4.8
NYHA Class III/IV (%)	65.0
CAD (%)	60.0
Previous CABG (%)	14.0

*Data represents a non-randomized sample of patients transfemorally implanted with a Portico valve using the FlexNav Delivery System between November 2018 and June 2019.

PORTICO I STUDY

The international, multicenter PORTICO I study is a prospective, single-arm, non-randomized post-market clinical investigation. The objective of the study is to assess long-term clinical outcomes of the Portico valve for treatment of severe, symptomatic aortic stenosis . Patients were high risk and were implanted via transfemoral access route. The study includes 61 centers in Europe (n=43), Canada (n=8), and Australia (n=10).[3-5]

BASELINE CHARACTERISTICS

	PORTICO VALVE (N=941)
Mean Age	82.4
STS Score (%)	5.8
EuroSCORE II (%)	15.7
NYHA Class III/IV (%)	64.0
CAD (%)	50.3
Previous CABG (%)	9.9

DELIVERABILITY REDEFINED.
TAVI REIMAGINED.

EXPERIENCE
REMARKABLE
DELIVERABILITY

PORTICO™ WITH FLEXNAV™
TAVI SYSTEM

References: 1. Fontana GP. Primary Outcomes of the PORTICO Randomized IDE Trial: Portico Vs. Commercially Available Transcatheter Aortic Valves in High and Extreme Risk Patients. Presented at TCT 2019. **2.** Fontana GP. Safety outcomes from the Portico IDE FlexNav Delivery System study of 100 high and extreme risk patients. Presented at London Valves Meeting 2019. **3.** Maisano F, et al. Early commercial experience from transcatheter aortic valve implantation using the Portico™ bioprosthetic valve: 30-day outcomes in the multicentre PORTICO-1 study. *EuroIntervention* 2018; 14-online publish-ahead-of-print August 2018. **4.** Søndergaard L, et al. One-Year Outcomes with a Self-Expanding, Repositionable Transcatheter Heart Valve in Severe Aortic Stenosis Patients: PORTICO-I. *Journal of the American College of Cardiology* (2018). **5.** Abbott, Data on File **6.** Manoharan G, et al. 1-Year Outcomes With the Evolut R Self-Expanding Transcatheter Aortic Valve. From the International FORWARD Study. *J Am Coll Cardiol Intv* 2018;11:2326–34. **7.** Wendler O, et al. SOURCE 3 Registry: Design and 30-Day Results of the European Post Approval Registry of the Latest Generation of the Sapien 3 Transcatheter Heart Valve. *Circulation.* Published online January 19, 2017. **8.** Wendler O, et al. SOURCE 3: 1-year outcomes post-transcatheter aortic valve implantation using the latest generation of the balloon-expandable transcatheter heart valve. *European Heart Journal* (2017) 0, 1–10.

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