



PORTICO™ TAVI SYSTEM

CLINICAL PERFORMANCE

HIGHLIGHTS

- Portico Valve with the FlexNav Delivery System is proven to deliver favourable outcomes, consistent with leading commercial valves in a high- or extreme-risk patient population^{1,2}
- Echo Core Lab data reveals positive hemodynamic outcomes^{1,2}
- PORTICO I real-world study data highlights outcomes comparable to leading TAVI valves³⁻⁸

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**

[^]in comparison to the Portico Loading System

CONCLUSIONS:

- The Portico with **FlexNav IDE cohort demonstrated favourable 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}:

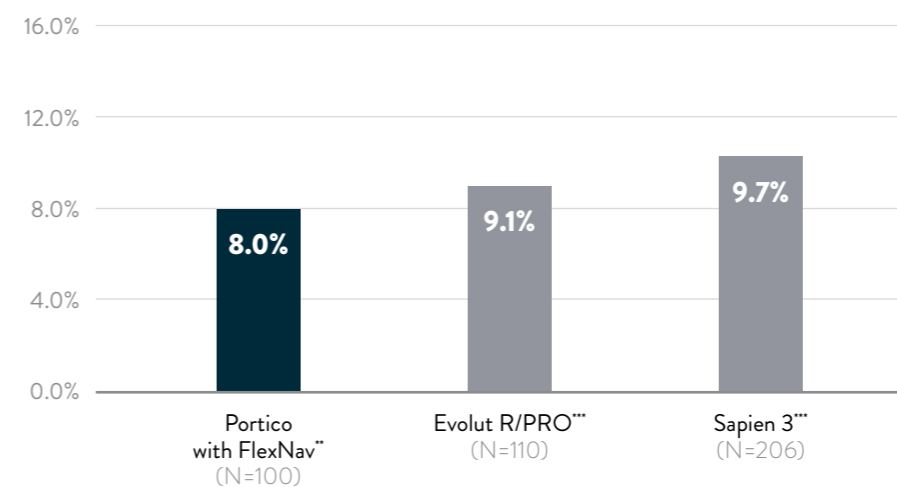


* Global cohort data represent a non-randomized sample of high- or extreme-risk patients that underwent an attempted Portico™ valve implant using the FlexNav™ delivery system via a transfemoral access approach between October 2018 and December 2019.

** 3.3% TAVI delivery system access site-related, 1.1% non-TAVI delivery system access site-related and 0.6% non-access site-related.

CLINICAL OUTCOMES (30 DAYS)

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



VALVE PERFORMANCE OF PORTICO WITH FLEXNAV

- Performance benchmarks with use of the next-generation FlexNav Delivery System compared favourably 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

* 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.

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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.

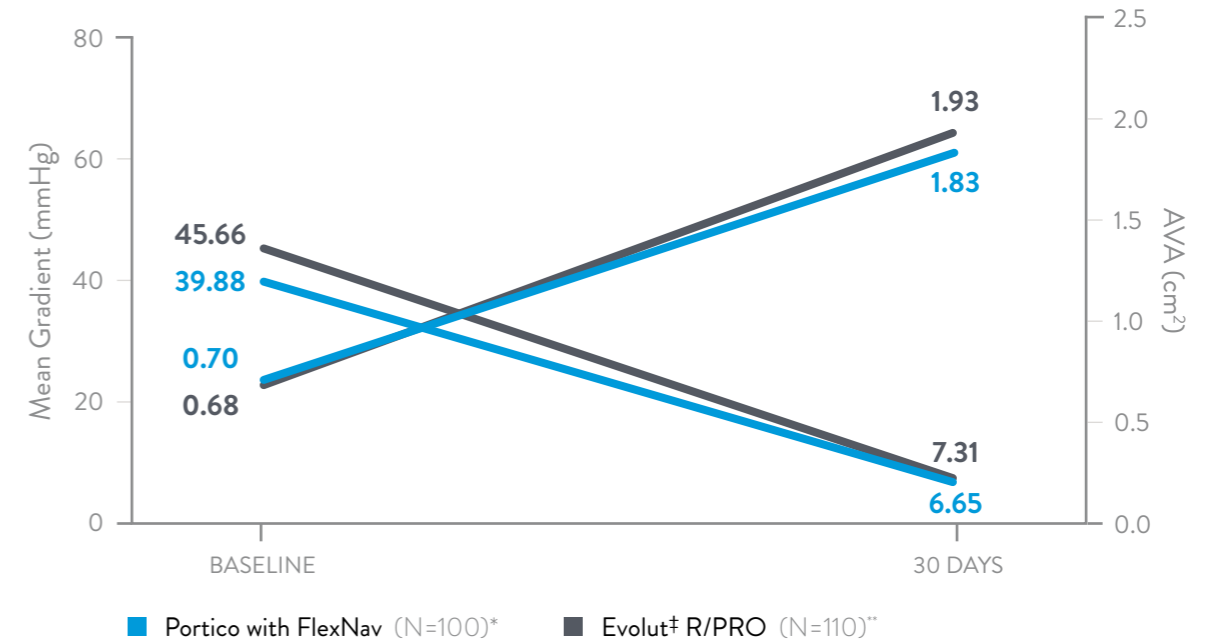
THE HEMODYNAMIC EDGE

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}

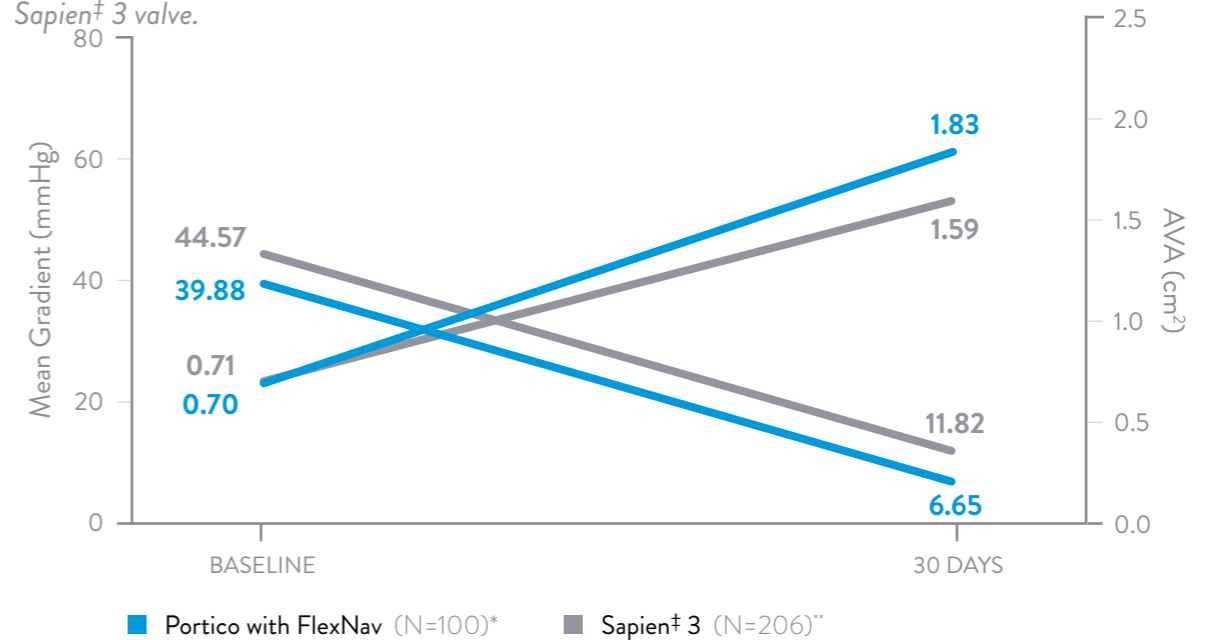
Intra-annular Portico valve compares favourably to the supra-annular Evolut[†] R/PRO valve.



OUTPERFORMING BALLOON-EXPANDABLE

VALVES^{1,2} Intra-annular Portico valve offers positive hemodynamics compared to intra-annular

Sapien[†] 3 valve.



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** 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.

EXPERIENCE MATTERS

The PORTICO I Post-Market Clinical Follow-up study*, using the previous-generation delivery system, demonstrates positive 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

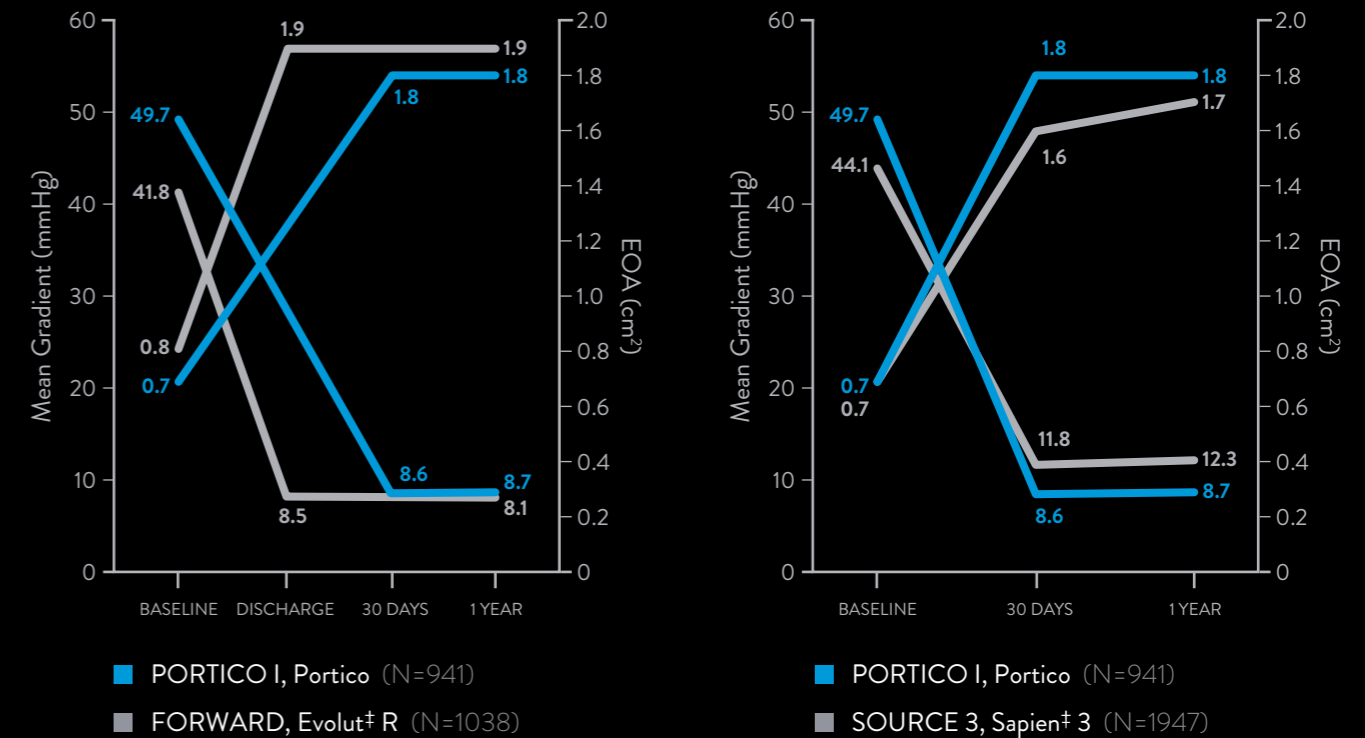
"Sites performing >15 procedures achieved a lower rate of moderate or higher PVL than sites with fewer procedures" (2.6% versus 7.2%, $p < 0.01$, 30-day comparison). —Maisano et. al EuroIntervention 2018

* The Portico I study was conducted via transfemoral access.

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SIGNIFICANT HEMODYNAMIC PERFORMANCE

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



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%

PORTICO I^{3,5}
Portico
(N=194)

Site ≤ 15 IMPLANTS

2.6%

PORTICO I^{3,5}
Portico
(N=495)

Site > 15 IMPLANTS

2.0%*

FORWARD⁶
Evolut[†] R
(N=813)

3.1%

SOURCE 3⁷
Sapien[†] 3
(N=N/A)

1 YEAR (% ≥ Moderate PVL)

2.6%

PORTICO I⁴
Portico
(N=573)

1.2%

FORWARD⁶
Evolut[†] R
(N=587)

2.6%

SOURCE 3⁸
Sapien[†] 3
(N=1007)

*at discharge



STUDY OVERVIEWS

PORTICO IDE FLEXNAV COHORT

The IDE FlexNav study was conducted as a separate arm of the PORTICO IDE trial. 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.^{1,2}

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

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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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