APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Country: *United States of America*

This public document

2. has been signed by CDR Cesar A. Perez, PhD.

3. acting in the capacity of Director, DRP2: Division of Establishment Support

4. bears the seal/stamp of U. S. Department of Health and Human Services

Certified

5. at Washington, D.C.

6. the eighth of November, 2021

7. by *Assistant Authentication Officer, United States Department of State*

8. No. 22005076-13

9. Seal/Stamp:

10. Signature:

Sonya N. Johnson

Digitally signe
Date: 2022.10.
Reason: Mold
Location: Mol

U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Certificate No. 100-10-2021

CERTIFICATE TO FOREIGN GOVERNMENT

In order to allow the importation of United States products into foreign countries , the U.S. Food and Drug Administration (FDA) certifies the following information concerning the product(s) to be exported listed below:

Name of Product(s)	**Name of Manufacturer/Distributor, Address**
See Attached List	See Attached List
(One Page)	(One Page)

The product(s) described above (and the manufacturing/distribution site(s) which produces/distributes it) is subject to the jurisdiction of the FDA under the Federal Food, Drug, and Cosmetic Act.

It is certified that the above product(s) may be marketed in, and legally exported from, the United States of America at this time. The manufacturing plant(s) in which the product(s) is produced is subject to periodic inspections. The last such inspection showed that the plant(s), at that time, appeared to be in substantial compliance with current good manufacturing practice requirements for the product(s) listed above.

Sincerely,

CDR Cesar A. Perez, PhD, Director
DRP2: Division of Establishment Support
Office of Regulatory Programs
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
U.S. Food and Drug Administration, DHHS

This certificate is valid from October 06, 2021 to October 05, 2023.

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Certificate to Foreign Government - Name of Manufacturer/Distributor Attachment Page 1 of 1

Name of Manufacturer

Manufacturing Site
Legal Manufacturer
Abbott Medical
Doing Business As
St. Jude Medical
177 County Road B E
Saint Paul, MN
USA 55117

Manufacturing Site
St. Jude Medical Costa Rica Ltda.
Edificio #44 Calle 0, Ave. 2
Zona Franca Coyol
El Coyol, Alajuela
COSTA RICA 1897-4050

----END OF MANUFACTURER/DISTRIBUTOR LIST----

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Name of Product(s)

Portico™ Transcatheter Heart Valve
Models: PRT-23, PRT-25, PRT-27, PRT-29
FlexNav™ Delivery System
Models: FNAV-DS-SM, FNAV-DS-LG
FlexNav™ Loading System
Models: FNAV-LS-SM, FNAV-LS-LG
----------END OF PRODUCT LIST----------

DELIVERABILITY REDEFINED.
TAVI REIMAGINED.

PORTICO™ WITH FLEXNAV™
TAVI SYSTEM

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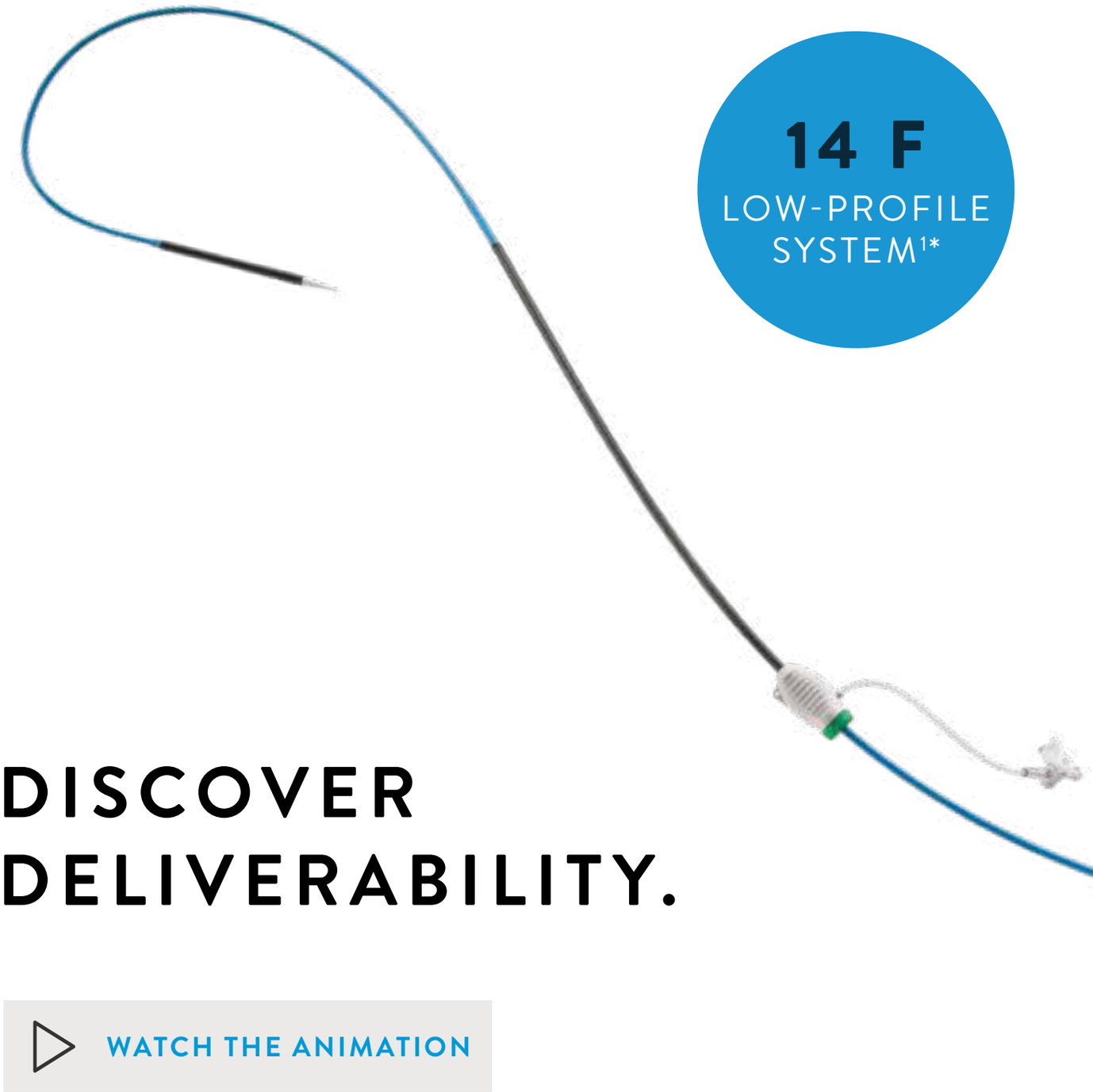
TAKE CONTROL.

THE MOMENT IS ALL YOURS.

THE FLEXNAV™ DELIVERY SYSTEM'S EXCEPTIONAL DESIGN WAS PURPOSEFULLY BUILT TO GIVE YOU COMPLETE, INDEPENDENT CONTROL OF VALVE DELIVERY.



14 F
LOW-PROFILE SYSTEM[1]*

DISCOVER DELIVERABILITY.

WATCH THE ANIMATION

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PORTICO™ WITH FLEXNAV™
TAVI SYSTEM

MOVING FORWARD. THINKING AHEAD.

AN EXPERIENCE LIKE NO OTHER.

Glide through anatomy.
Secure stable, predictable valve placement.
Position the valve exactly where you intend.

A SYSTEM DESIGNED FOR PERFORMANCE.

Navigate with ease.
Feel the calm during valve deployment.
Make every procedure your best one yet.

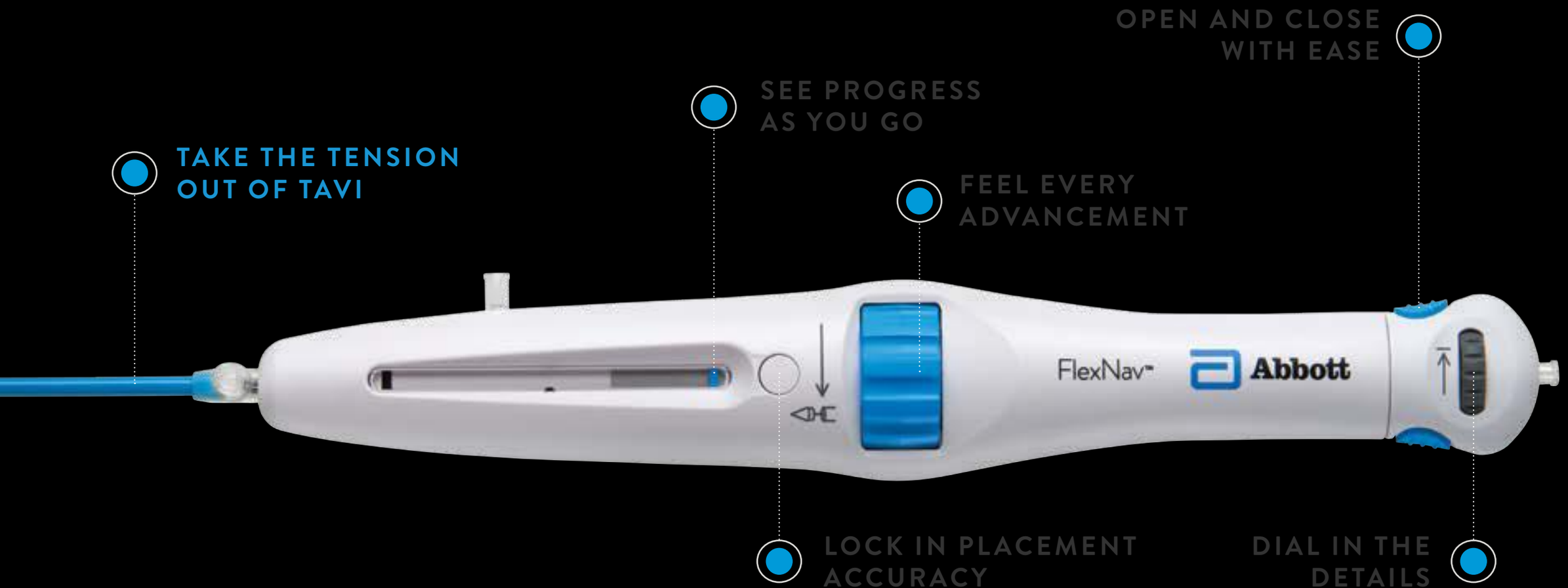
A CLEAR CHOICE FOR EVERY TAVI CASE.

From routine to complex cases.
Through femoral or alternative access approaches.
Discover your new workhorse valve.

*14 F equivalent integrated sheath diameter.

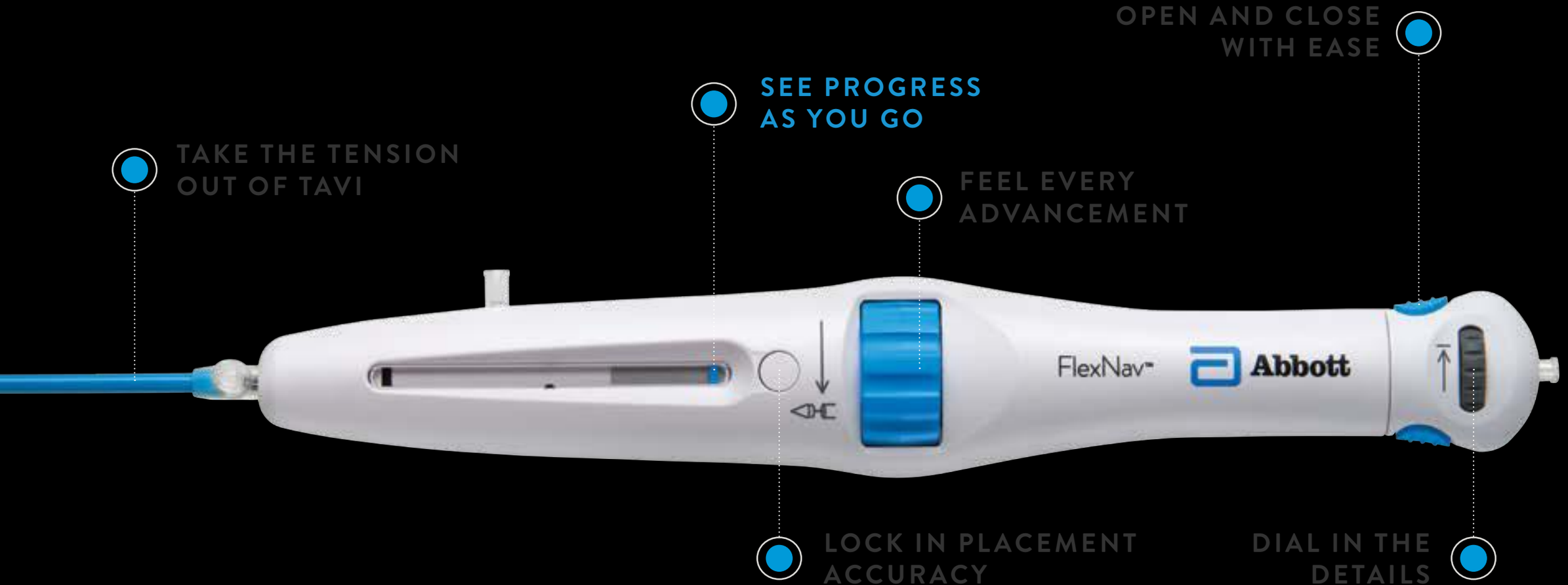
BIG THINKING, DOWN TO THE SMALLEST DETAIL.

BIG THINKING, DOWN TO THE SMALLEST DETAIL.



The stability layer ensures stable, predictable valve deployment to achieve accurate valve placement.

BIG THINKING, DOWN TO THE SMALLEST DETAIL.



A deployment indicator gives you a clear visualization of the valve's deployment progress.

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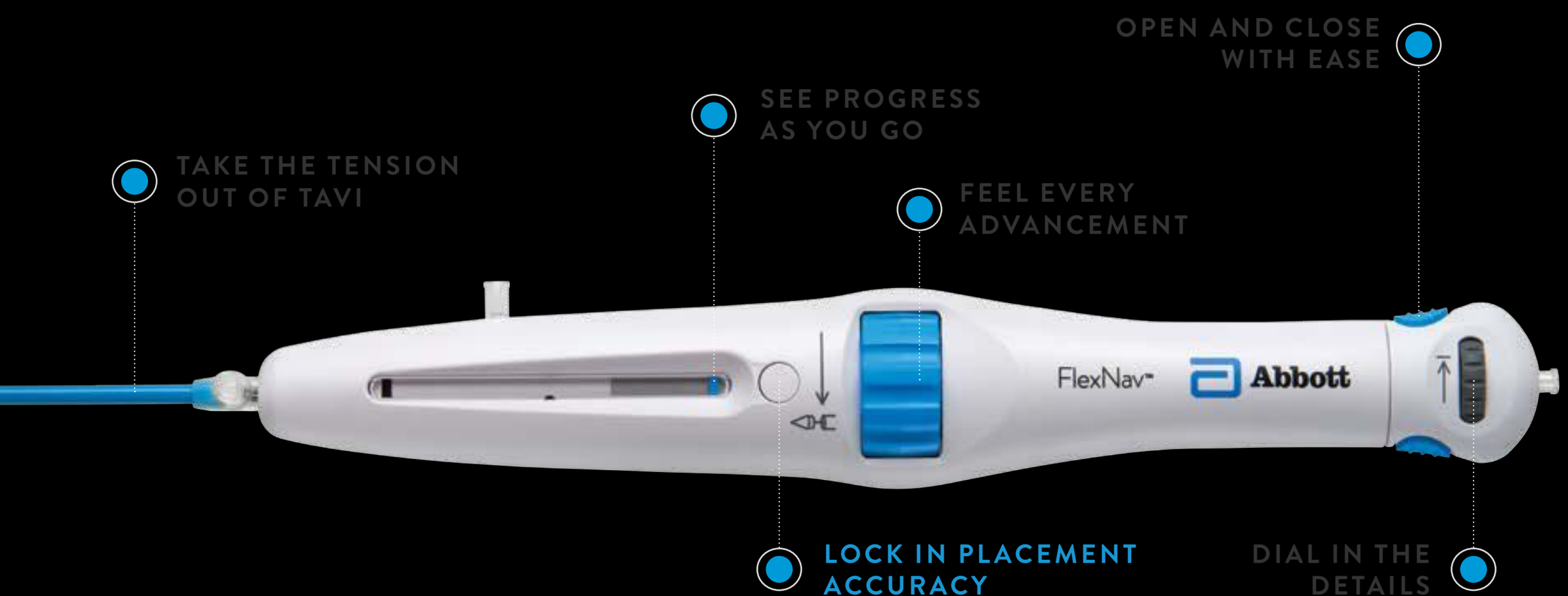

The automatic lock button prevents full valve deployment until you've got the valve right where you want it.

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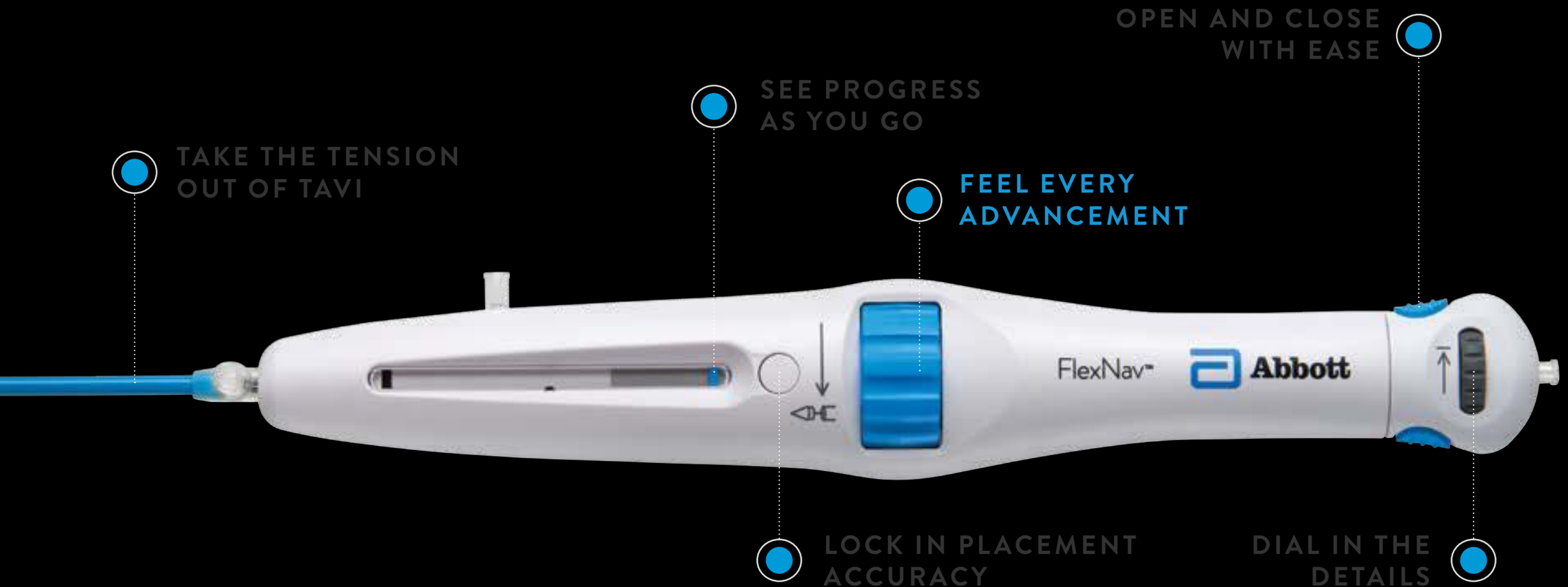
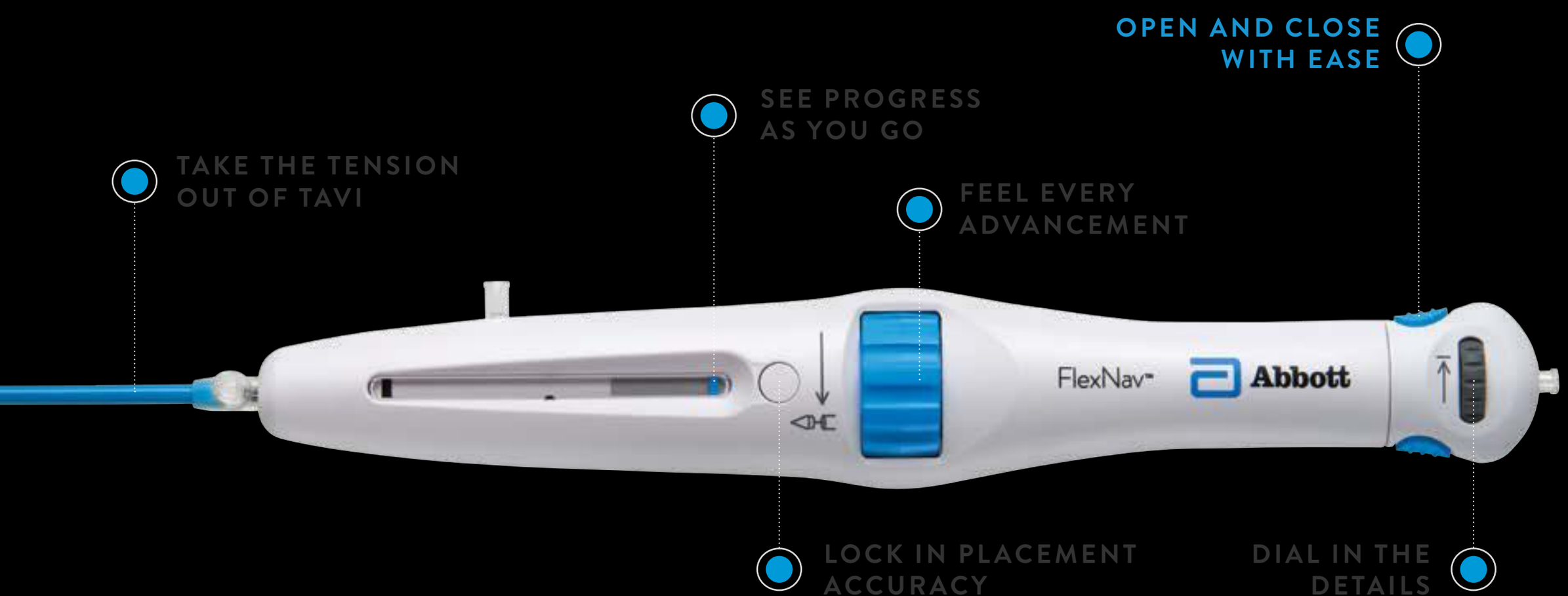


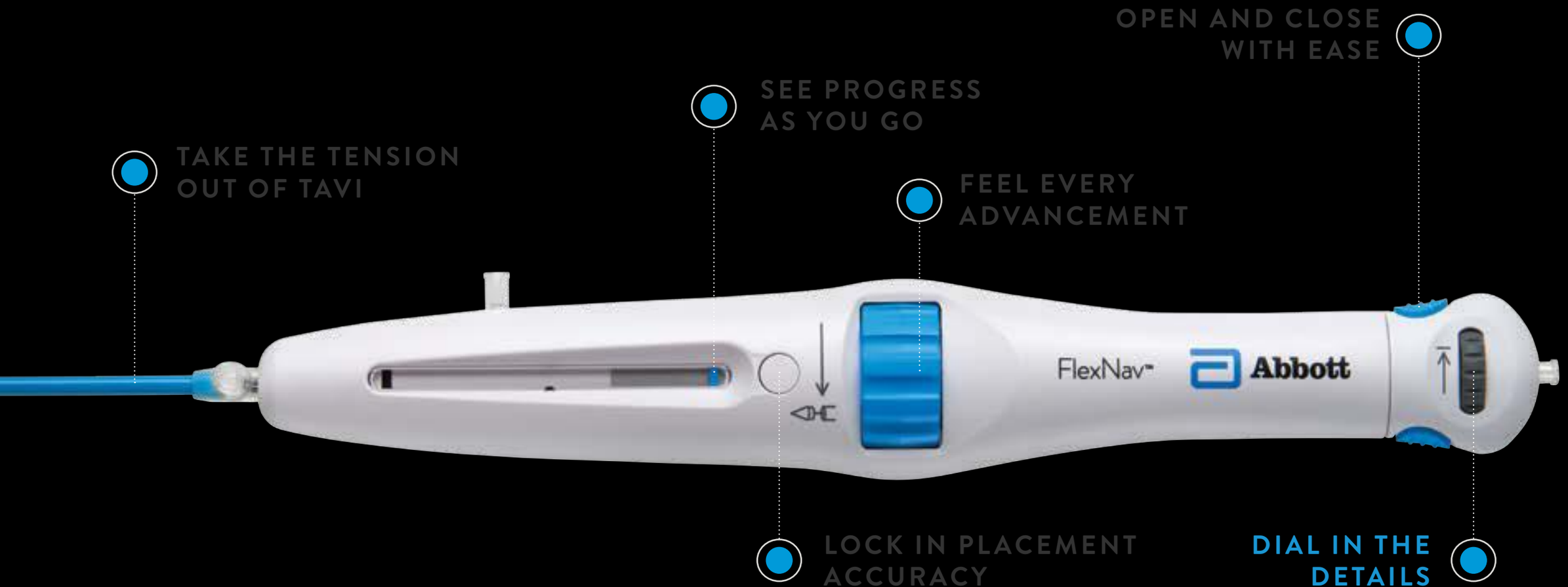
The simple deployment wheel provides both audible and tactile feedback as you deploy the valve.

BIG THINKING, DOWN TO THE SMALLEST DETAIL.



Two macro-slide buttons make it easy for you to open and close the distal end of the delivery system during valve loading and post-deployment.

BIG THINKING, DOWN TO THE SMALLEST DETAIL.



With the unique micro-adjustment wheel, you can close gaps between the valve capsule and the atraumatic nosecone.

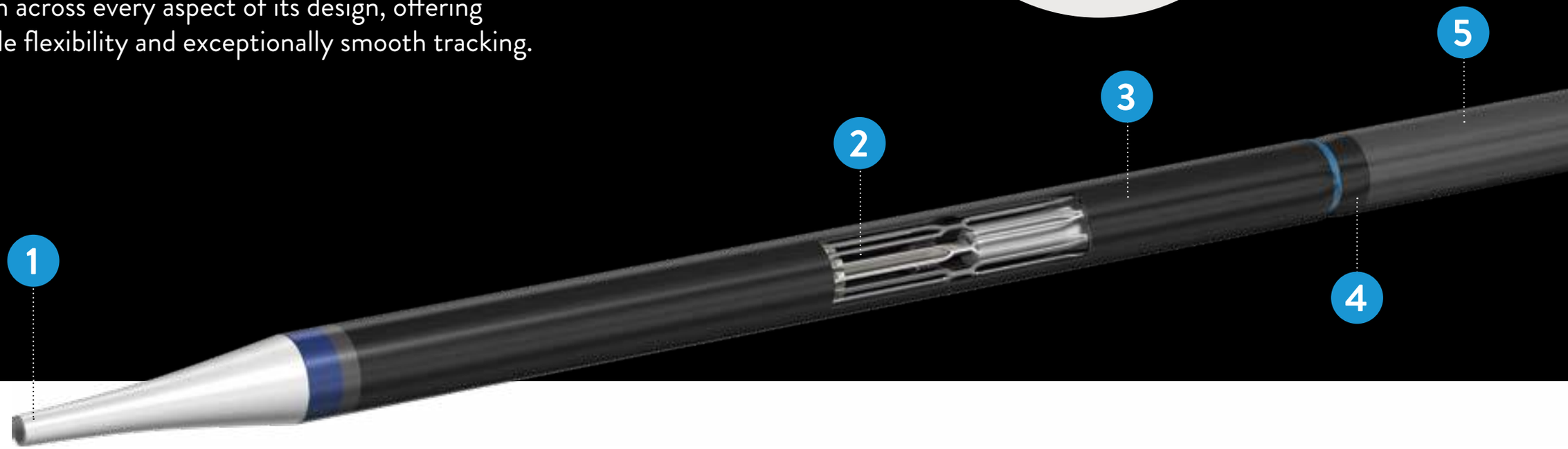
LOOK CLOSER.

DELIVERABILITY IS IN THE DETAILS.

The Portico™ with FlexNav™ TAVI system brings together innovation across every aspect of its design, offering remarkable flexibility and exceptionally smooth tracking.

3D FLEXIBILITY. INFINITE POSSIBILITY.

The FlexNav™ delivery system offers three-dimensional flexibility at the distal end and throughout its entire working length.



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*14 F equivalent integrated sheath diameter.

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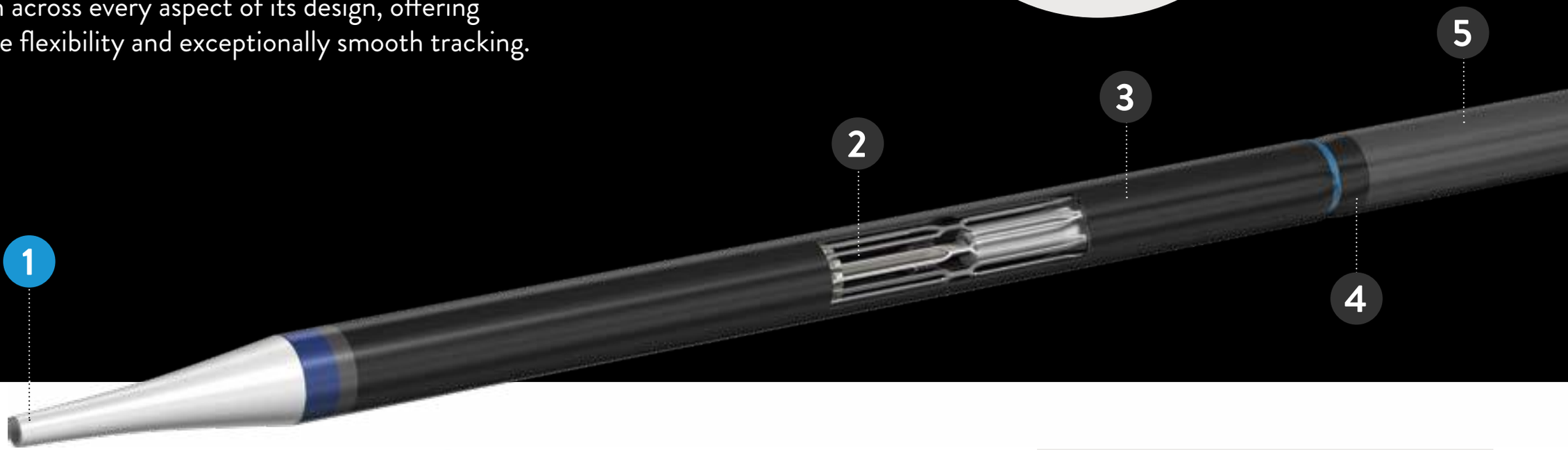

1 ATRAUMATIC NOSECONE

Atraumatic nosecone and smooth transitions are designed to reduce vascular complications and prevent calcium dislodgement.

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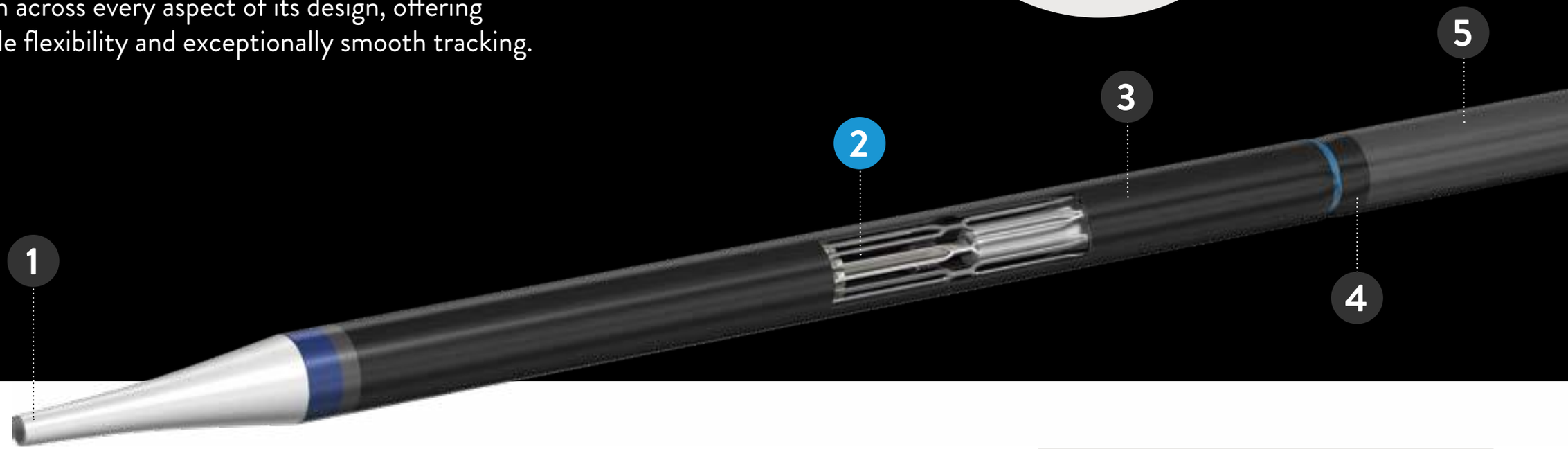

2 LARGE-CELL FRAMEWORK

The large-cell framework of the Portico™ valve reduces metal mass, resulting in a more flexible capsule.

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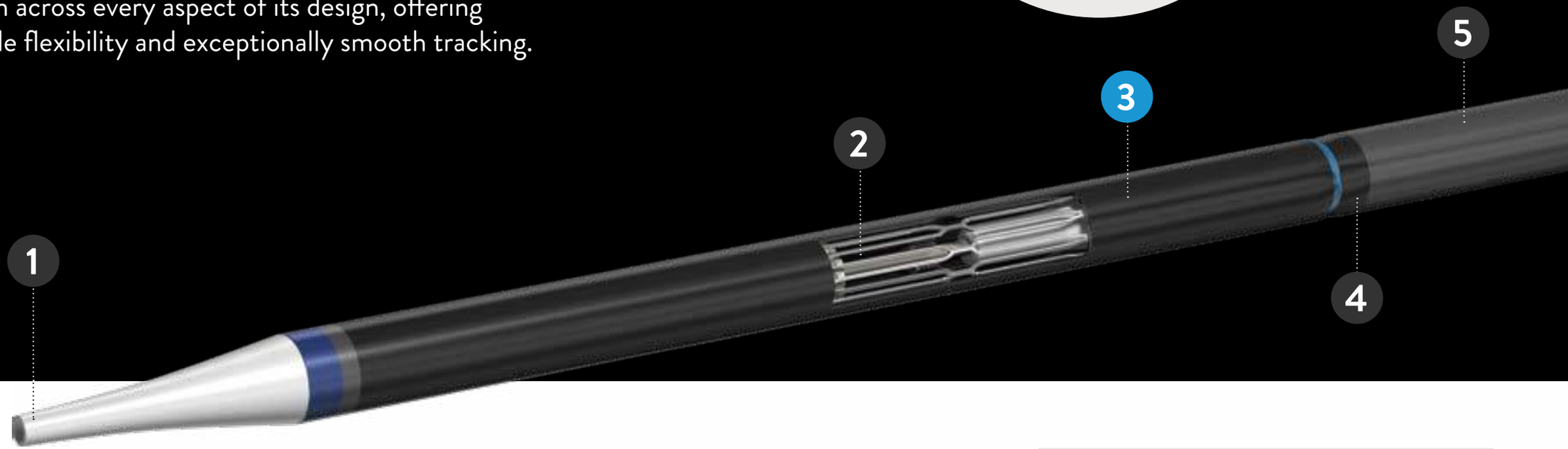

3 FLEXIBLE CAPSULE

The capsule is more flexible because it does not require bilateral metal rails or extra nitinol braiding, resulting in enhanced flexibility.[2]

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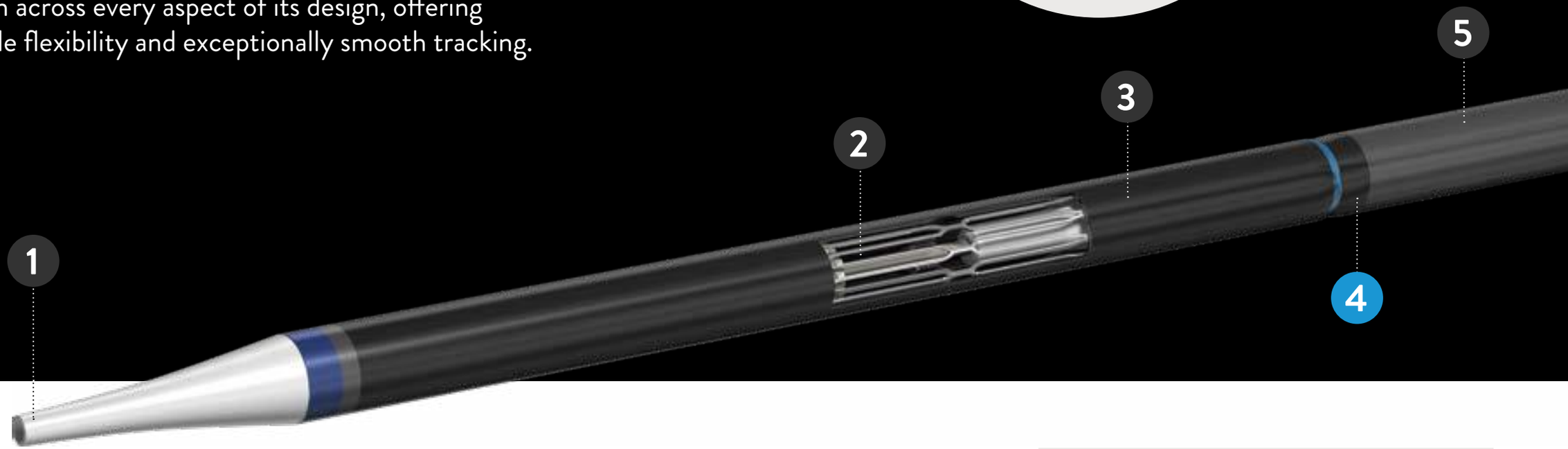

4 HYDROPHILIC COATING

Hydrophilic coating reduces friction by 98%,[3] providing lubricity to guide the system through vasculature.

*14 F equivalent integrated sheath diameter.

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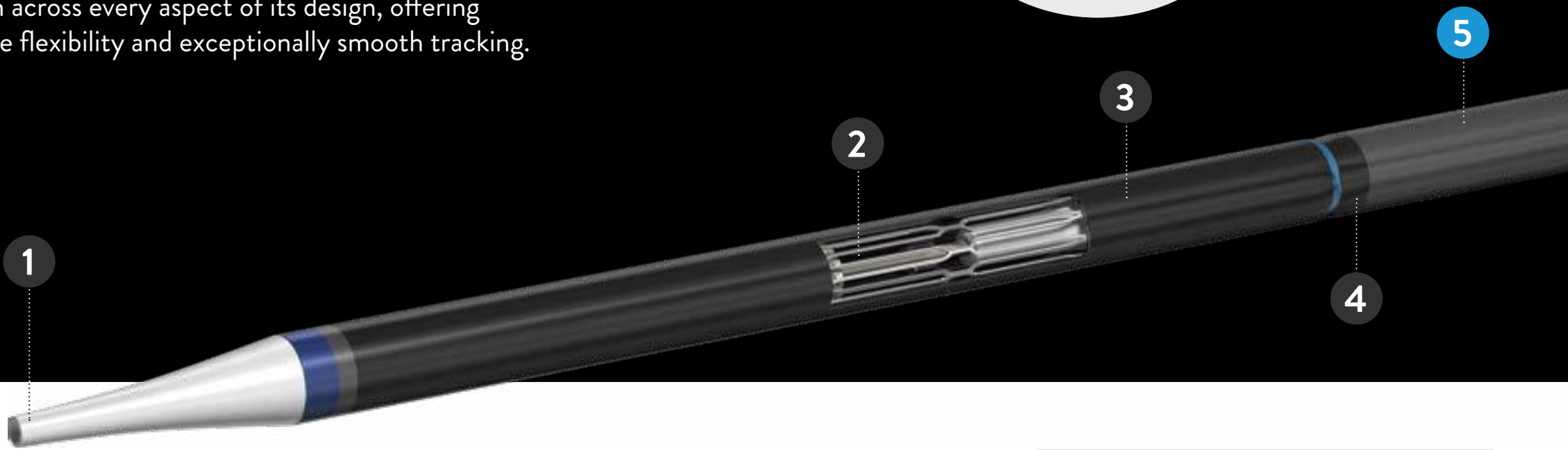
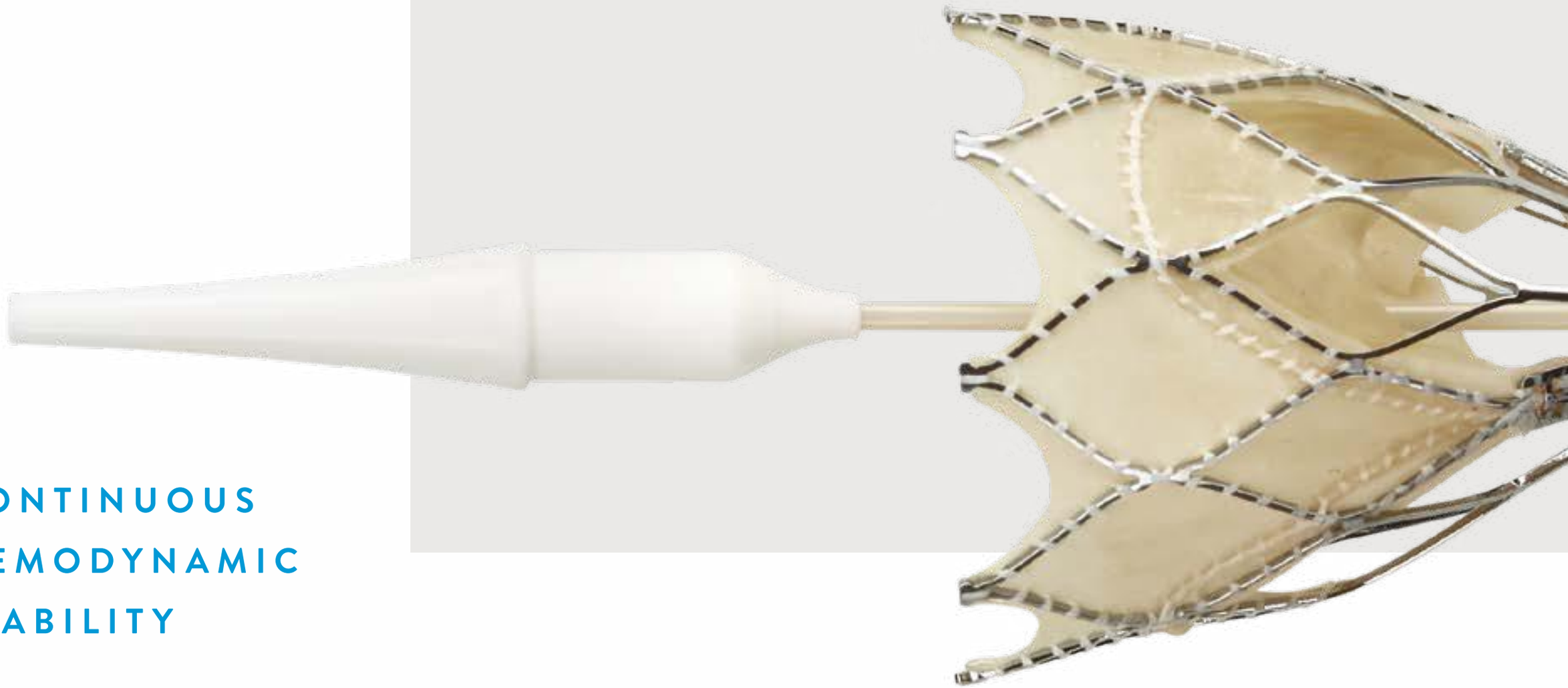


Integrated sheath for low 14 F delivery profile.[1]*

5 INTEGRATED SHEATH

*14 F equivalent integrated sheath diameter.



CONTINUOUS HEMODYNAMIC STABILITY

STABLE FROM THE START.

EARLY LEAFLET FUNCTIONALITY. NO RAPID PACING.

Intra-annular leaflet position in a self-expanding valve provides early valve function and hemodynamic stability throughout the procedure—for calm and controlled deployment, without compromise.

THINKING AHEAD

LARGE-CELL GEOMETRY AND INTRA-ANNULAR VALVE POSITION PRESERVE CORONARY ACCESS.

EVERY ASPECT OF THE PORTICO™ WITH FLEXNAV™ TAVI SYSTEM WAS DESIGNED TO HELP YOU PLACE THE VALVE **ON TARGET, EVERY TIME.**

BUT IN CASE YOU NEED TO MAKE A MOVE, REST ASSURED.

RECAPTURABLE*

REPOSITIONABLE*

RETRIEVABLE*

*Until fully deployed.

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FEEDBACK FROM FLEXNAV™ DELIVERY SYSTEM USERS*

OVERALL DELIVERABILITY

“It was very easy to use. We saved two French sizes of the sheath compared to the previous system. The control of the delivery system was absolutely better. It’s a big advantage in the development of the TAVI procedure with the Portico™ valve.”

INTERVENTIONAL CARDIOLOGIST
Italy

HEAR FEEDBACK FROM FLEXNAV™ DELIVERY SYSTEM USERS

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FEEDBACK FROM FLEXNAV™ DELIVERY SYSTEM USERS*

OVERALL FLEXIBILITY

“The system is a major advancement. With release, it didn’t move at all. And this was in a relatively horizontal aorta. We were able to end up being two to three mm in both the non-coronary and the left coronary side. Perfect implant. Very impressed. Big improvement.”

INTERVENTIONAL CARDIOLOGIST
United States of America

HEAR FEEDBACK FROM FLEXNAV™ DELIVERY SYSTEM USERS

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FEEDBACK FROM FLEXNAV™ DELIVERY SYSTEM USERS*

PLACEMENT ACCURACY

“A key element of this is the stability of the delivery. Having done a lot of cases before, I and the team had a really good understanding of the movements of the valve when it was being released or retracted. But here, with the FlexNav™ system, it is just stable throughout the whole delivery.”

INTERVENTIONAL CARDIOLOGIST
Australia

HEAR FEEDBACK FROM FLEXNAV™ DELIVERY SYSTEM USERS

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FEEDBACK FROM FLEXNAV™ DELIVERY SYSTEM USERS*

DELIVERABILITY IN TORTUOUS ANATOMY

“The biggest benefit is the ability for the valve to be advanced even through very tortuous anatomies. The hydrophilic coating of the delivery system allows the valve and the delivery system to swim through arches and accesses without any difficulty at all.”

INTERVENTIONAL CARDIOLOGIST
United Kingdom

HEAR FEEDBACK FROM FLEXNAV™ DELIVERY SYSTEM USERS

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PORTICO™ TAVI SYSTEM

CLINICAL PERFORMANCE

- Portico™ with FlexNav™ TAVI system is proven to deliver excellent safety outcomes, consistent with leading commercial valves in a high- or extreme-risk patient population[4,5]
- Echo Core Lab data reveals excellent hemodynamic outcomes with the Portico™ valve.[4,5]
- PORTICO I real-world study data highlights outcomes comparable to leading TAVI valves[6-11]

STUDY PROFILE

- The Global Portico™ with FlexNav™ TAVI System cohort includes data from patients enrolled in the IDE FlexNav DS study (N=134) and the FlexNav CE Mark Study (N=46)
- 180 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
- Outcomes reported in the Global Portico with FlexNav TAVI system cohort were descriptively compared to a subset of randomized patients implanted with contemporary valve models (Sapein‡ 3 or Evolut‡ R/PRO) as part of the PORTICO IDE trial; all subjects followed similar study eligibility criteria, study oversight (including same Echo Core Lab and CEC), study assessments and follow-up schedule

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NEW DATA CONFIRMS PERFORMANCE OF PORTICO WITH FLEXNAV TAVI SYSTEM[4,5]

CONCLUSIONS:

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

STUDY OVERVIEW

The Global Portico™ with FlexNav™ TAVI System cohort includes data from patients enrolled in the IDE FlexNav DS study (N=134) and the FlexNav CE Mark Study (N=46). 180 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.[4,5]

BASELINE CHARACTERISTICS

	PORTICO WITH FLEXNAV TAVI SYSTEM (N=180)*
Mean Age	85.1
STS Score (%)	5.3
EuroSCORE II (%)	4.8
NYHA Class III/IV (%)	62.2
Coronary Artery Disease (%)	58.9
Previous CABG (%)	13.9

*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.

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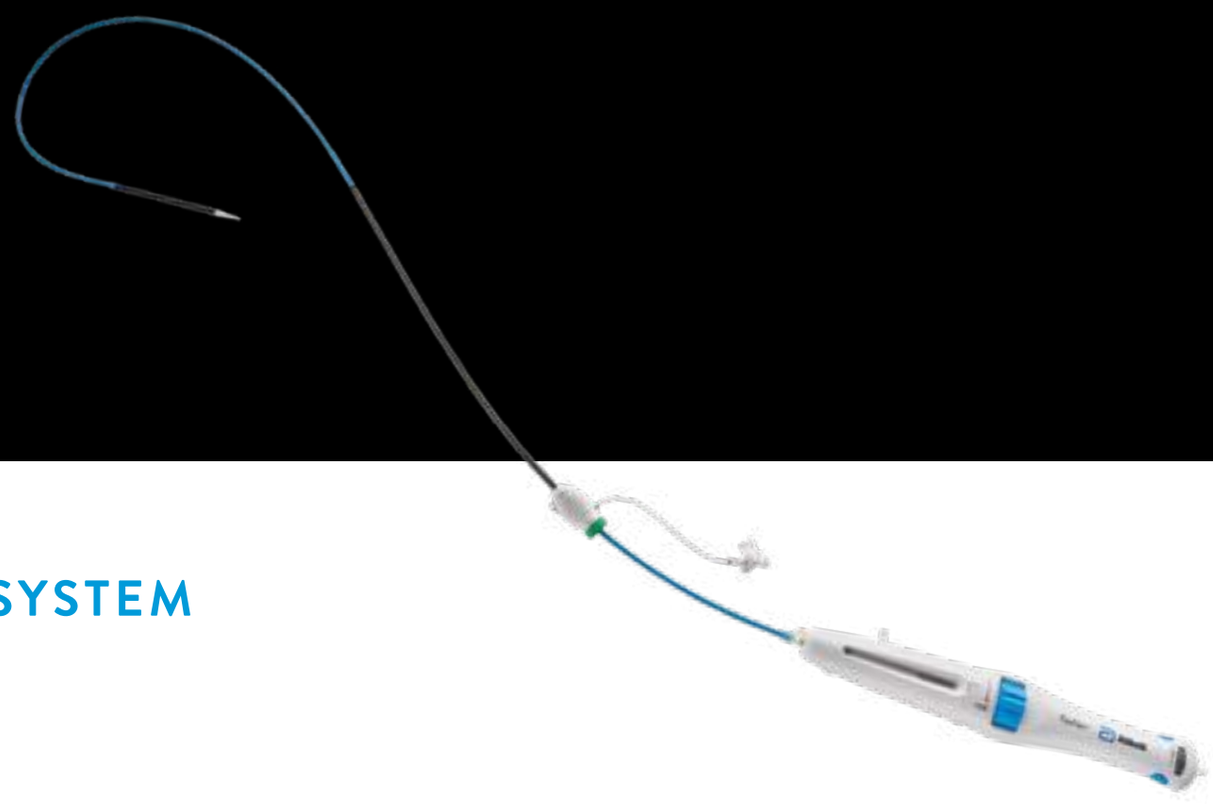
NEW DATA CONFIRMS PERFORMANCE OF PORTICO WITH FLEXNAV TAVI SYSTEM[5]



THE GLOBAL PORTICO WITH FLEXNAV TAVI SYSTEM COHORT DEMONSTRATED THE FOLLOWING OUTSTANDING OUTCOMES*[5]

0.6%
ALL-CAUSE MORTALITY

1.1%
DISABLING STROKE

0.0%
ACUTE KIDNEY INJURY STAGE III

3.9%
LIFE-THREATENING BLEEDING

5.0%
MAJOR VASCULAR COMPLICATIONS†

* 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. n = 180. These outcomes are at 30 days post index procedure and according to VARC 2 criteria.

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

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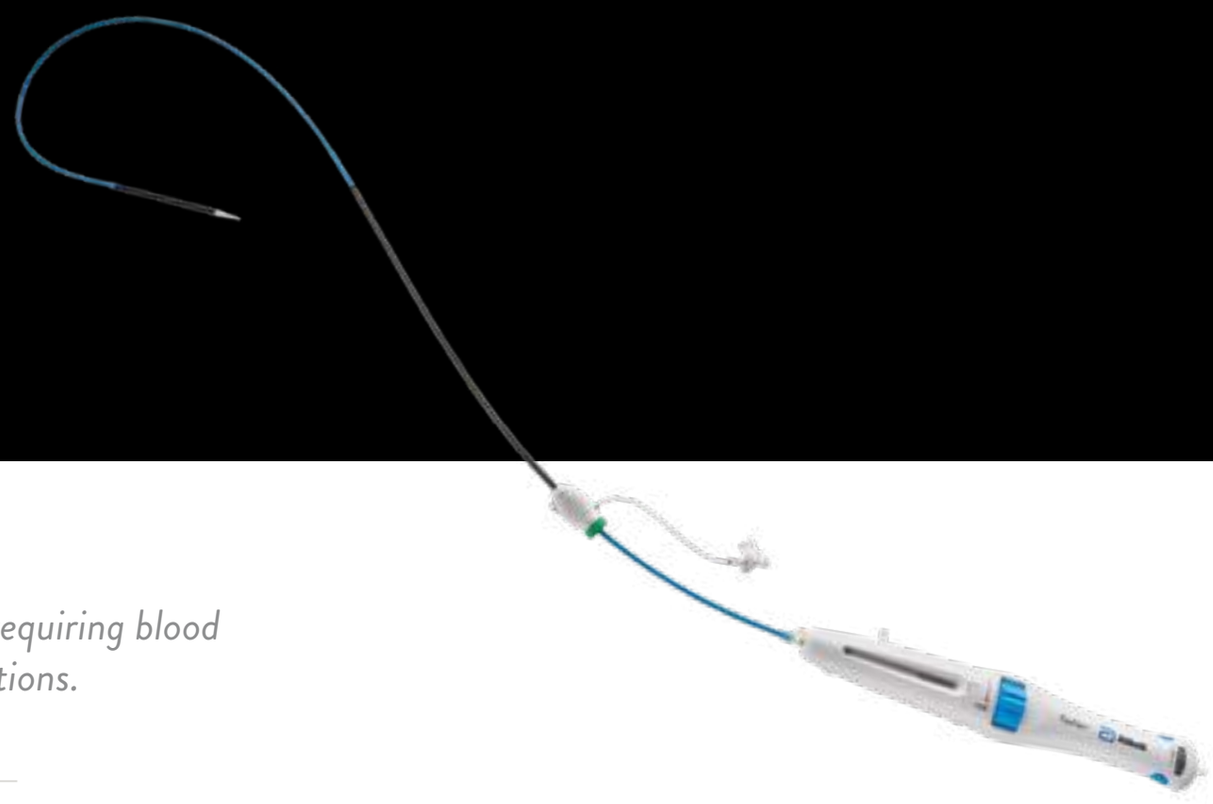
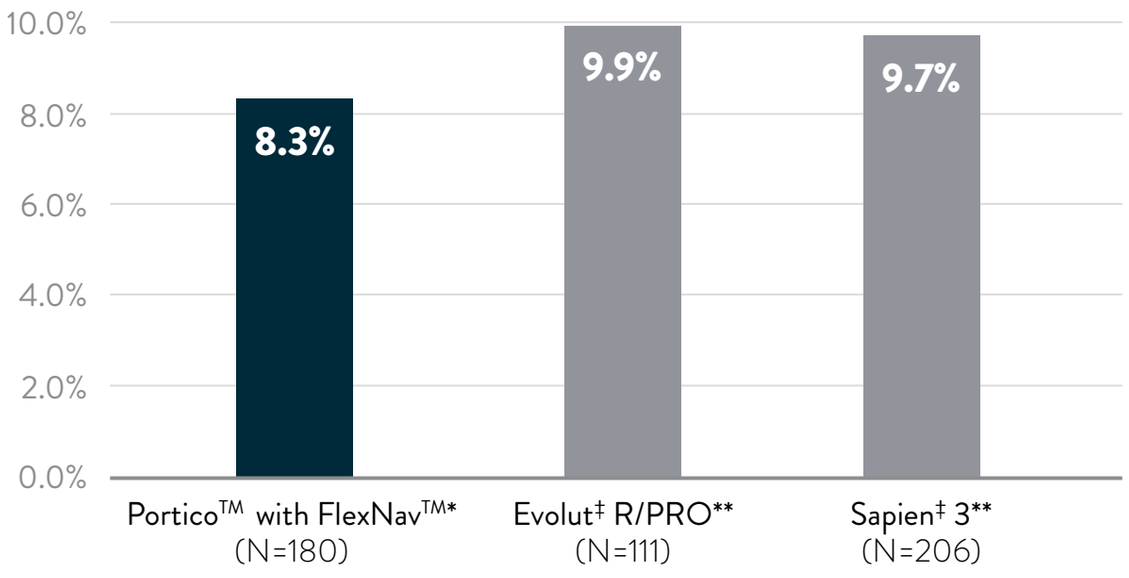
NEW DATA CONFIRMS PERFORMANCE OF PORTICO WITH FLEXNAV TAVI SYSTEM[4,5]



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 THE FLEXNAV™ DELIVERY SYSTEM

- Safety benchmarks with use of the next-generation FlexNav™ delivery system compared favorably to Sapien‡ 3 and Evolut‡ R/PRO

NOTE: Data not from head-to-head studies. Data differences depicted between these trials may not be directly comparable, statistically significant, or clinically meaningful due to differences in trial protocols, endpoints, and/or patient populations. Data provided for informational purposes only.

*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.

**Data represent a subset of high- or extreme-risk patients that underwent an attempted Evolut‡ R, Evolut‡ PRO or Sapien‡ 3 valve implant via a transfemoral or alternative access approach between May 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[4,5]

30-DAY COMPARISON

	PORTICO™ WITH FLEXNAV™ (N=180)*	EVOLUT‡ R/PRO (N=111)**	SAPIEN‡ 3 (N=206)**
All-Cause Mortality (%)	0.6	1.8	0.0
Disabling Stroke (%)	1.1	0.9	1.0
Life-Threatening Bleeding (%)	3.9	5.4	3.4
Major Vascular Complications (%)	5.0†	7.2	7.3
New Permanent Pacemaker (%)	15.4	18.8	5.4
Acute Kidney Injury Stage III (%)	0.0	1.8	0.0
Mean Gradient (mmHg)	7.1	7.3	11.8
Aortic Valve Area (cm^2)	1.8	1.9	1.6
Moderate or Greater PVL (%)	4.1	4.0	1.6

NOTE: Data not from head-to-head studies. Data differences depicted between these trials may not be directly comparable, statistically significant, or clinically meaningful due to differences in trial protocols, endpoints, and/or patient populations. Data provided for informational purposes only.

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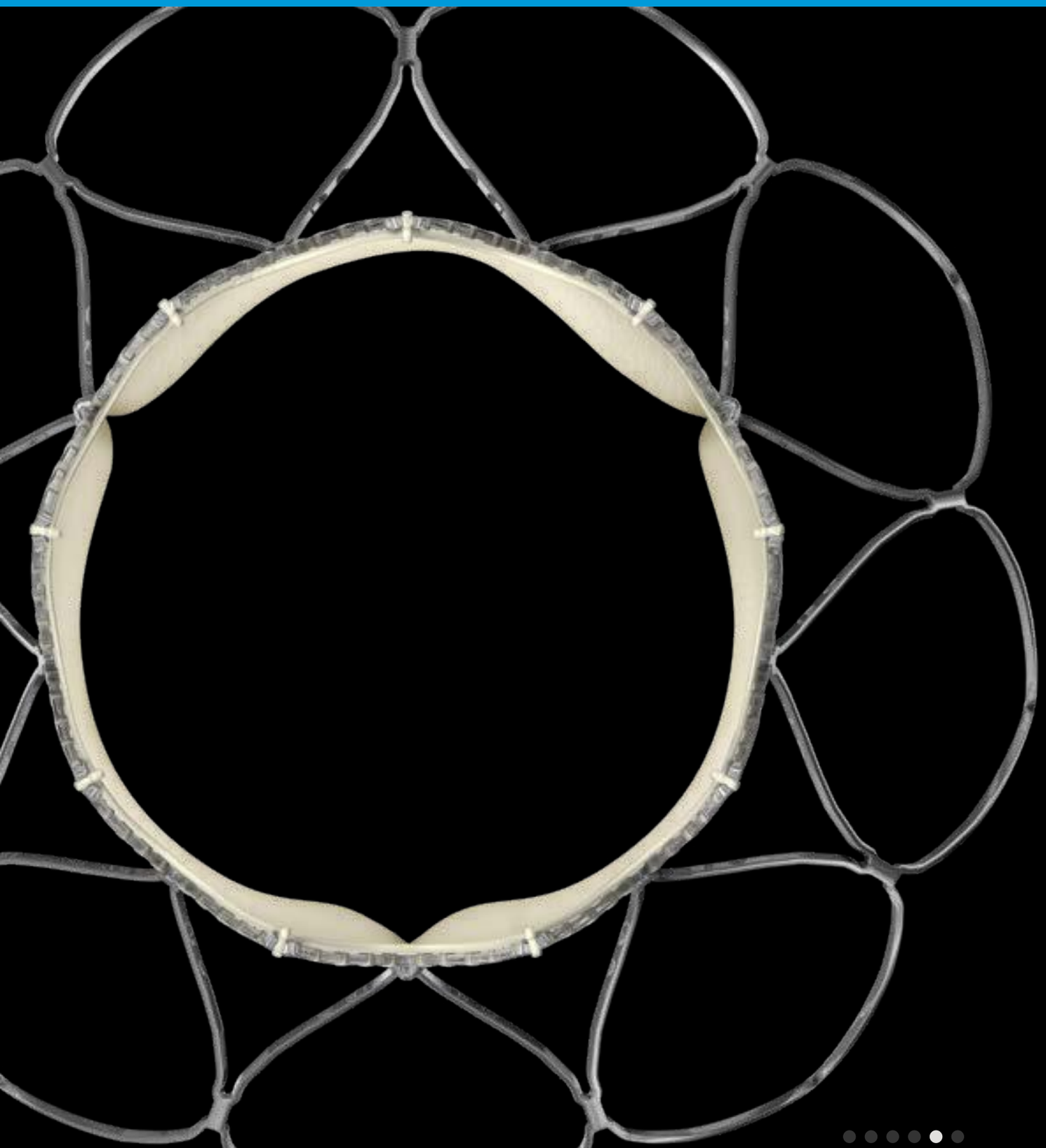

ECHO CORE LAB DATA

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.[4,5]

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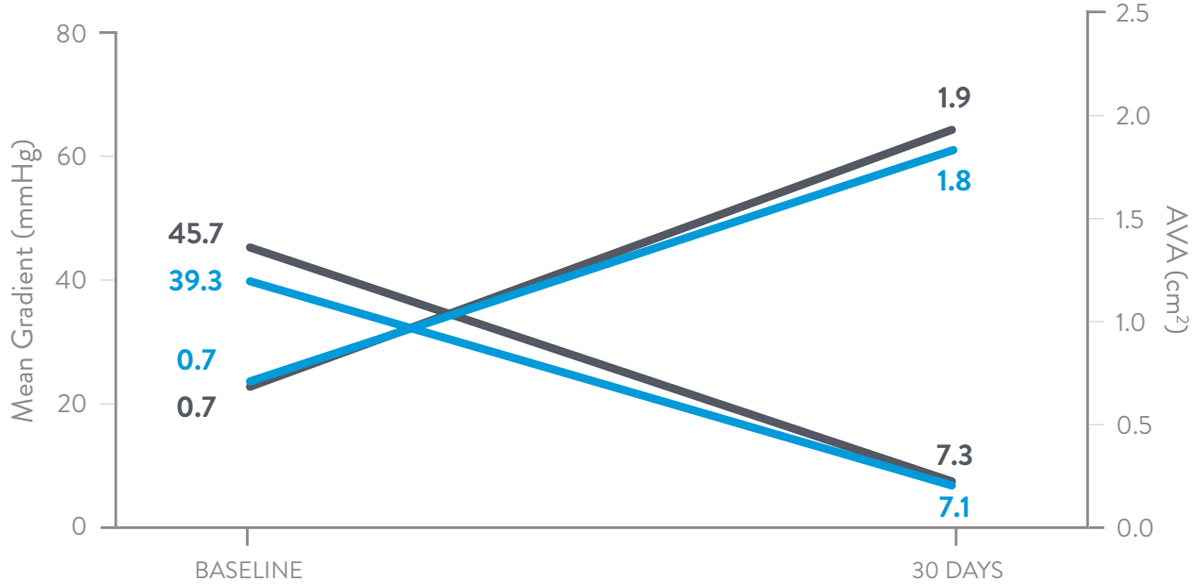
SELF-EXPANDING VALVES. SINGLE-DIGIT GRADIENTS.[4,5]

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

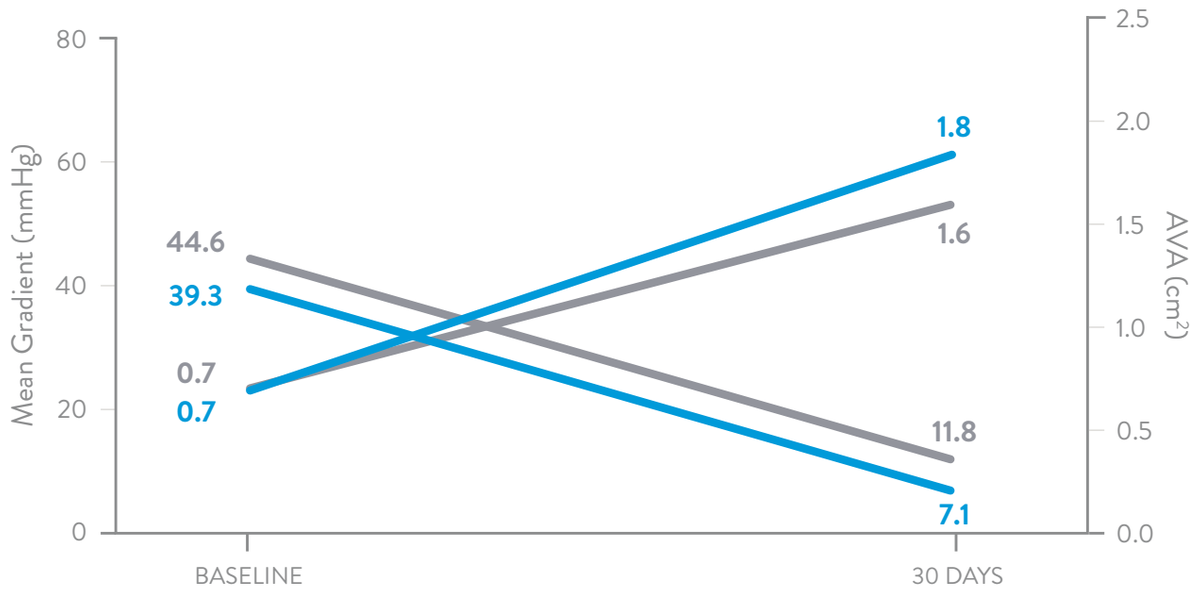
- Portico™ with FlexNav™ (N=180)*
- Evolut‡ R/PRO (N=110)**



OUTPERFORMING BALLOON-EXPANDABLE VALVES[4,5]

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

- Portico with FlexNav (N=180)*
- Sapien‡ 3 (N=206)**



NOTE: Data not from head-to-head studies. Data differences depicted between these trials may not be directly comparable, statistically significant, or clinically meaningful due to differences in trial protocols, endpoints, and/or patient populations. Data provided for informational purposes only.

*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.

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

REAL-WORLD POST-MARKET STUDIES

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.[6-11]

30-DAY COMPARISON

	PORTICO I[6] Portico™ valve (N=941)	FORWARD[9] Evolut‡ R (N=1038)	SOURCE 3[10] 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
Acute Kidney Injury Stage II-III (%)	3.0	1.1	1.1
New Permanent Pacemaker (%)	18.7	20.2	12.0

NOTE: Data not from head-to-head studies. Data differences depicted between these trials may not be directly comparable, statistically significant, or clinically meaningful due to differences in trial protocols, endpoints, and/or patient populations. Data provided for informational purposes only.

*The Portico I study was conducted via transfemoral access.

Information contained herein for **DISTRIBUTION outside of the U.S. ONLY.**
Always check the regulatory status for the device in your region.

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).[6-8]

BASELINE CHARACTERISTICS

	PORTICO VALVE (N=941)
Mean Age	82.4
STS Score (%)	5.8
Logistic EuroSCORE I (%)	15.7
NYHA Class III/IV (%)	64.0
Coronary Artery Disease (%)	50.3
Previous CABG (%)	9.9

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PORTICO I POST-MARKET CLINICAL FOLLOW-UP

LOW RATES OF CLINICALLY SIGNIFICANT PVL

At 30 days and 1 year, Portico™ valve demonstrates low rates of moderate or higher PVL consistent with other leading TAVI valves.[6-11]

IMPLANTER EXPERIENCE IMPACTS PVL

FROM A PORTICO I POST HOC ANALYSIS:

"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

30 DAYS (% ≥ Moderate PVL)

PORTICO I[6,8] Portico valve (N=194) Site ≤ 15 IMPLANTS	PORTICO I[6,8] Portico valve (N=495) Site > 15 IMPLANTS	FORWARD[9] Evolut‡ R (N=813)	SOURCE 3[10] Sapien‡ 3 (N=N/A)
7.2%	2.6%	2.0%*	3.1%

1 YEAR (% ≥ Moderate PVL)

PORTICO I[7] Portico valve (N=573)	FORWARD[9] Evolut‡ R (N=587)	SOURCE 3[11] Sapien‡ 3 (N=1007)
2.6%	1.2%	2.6%

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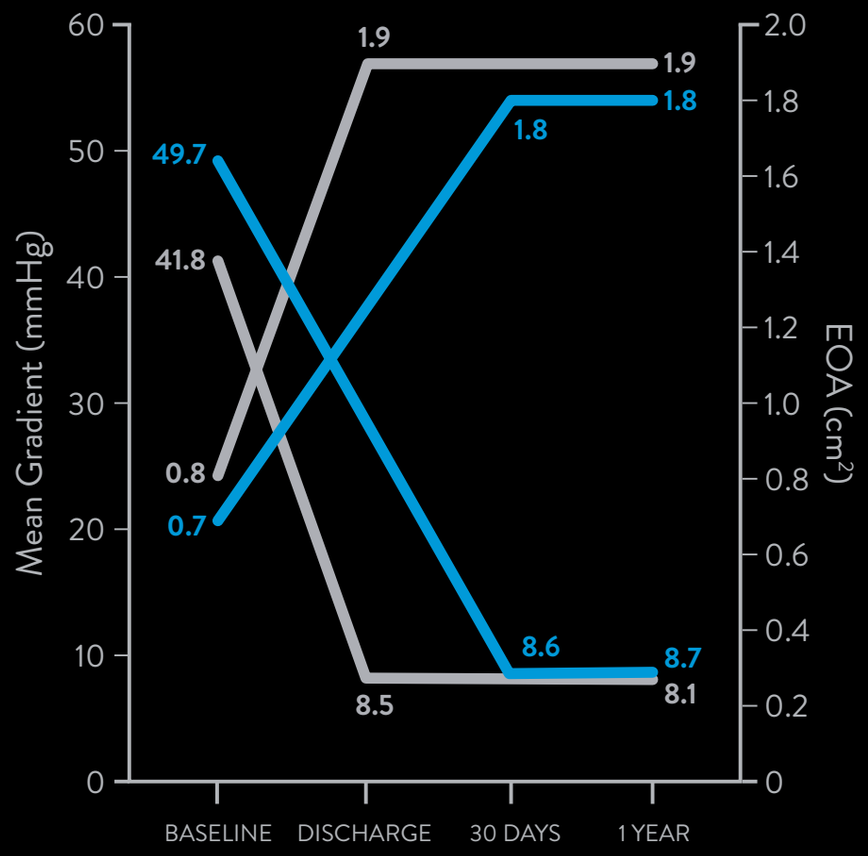
*At discharge

PORTICO I POST-MARKET CLINICAL FOLLOW-UP

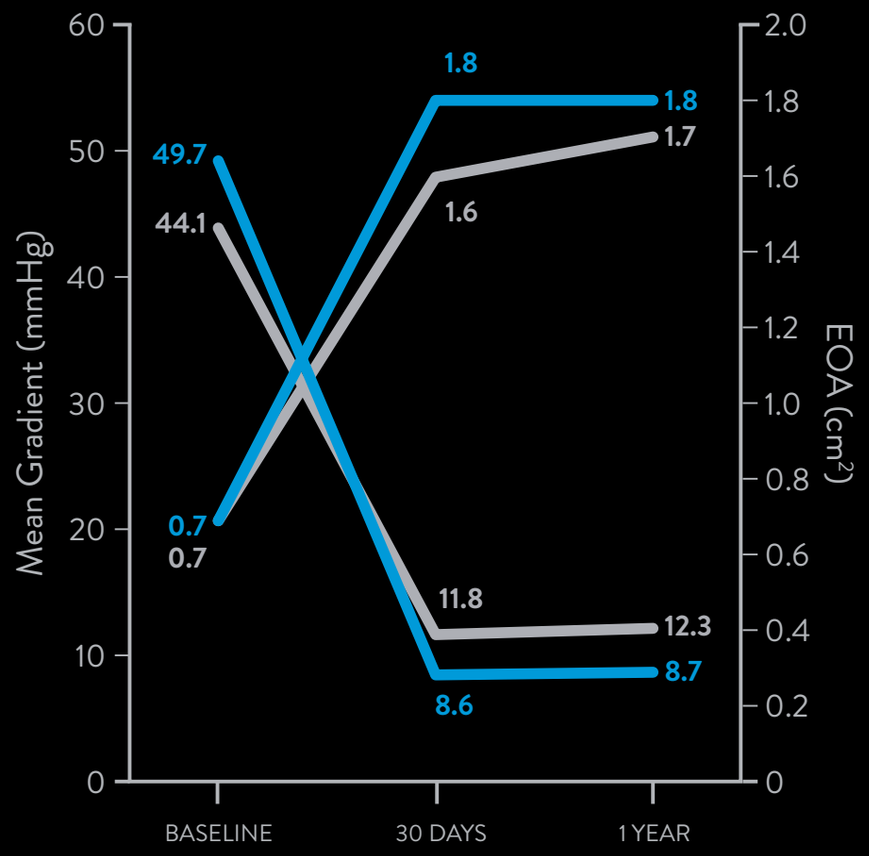
EXCELLENT HEMODYNAMIC PERFORMANCE

At 30 days and 1 year, Portico™ valve demonstrates single-digit mean gradients and large EOAs.[6-11]



■ PORTICO I, Portico valve (N=941)

■ FORWARD, Evolut‡ R (N=1038)



■ PORTICO I, Portico valve (N=941)

■ SOURCE 3, Sapien‡ 3 (N=1947)

Information contained herein for **DISTRIBUTION outside of the U.S. ONLY.**
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PORTICO TRANSCATHETER AORTIC VALVE

23mm

25mm

27mm

29mm

Catalog Number	Valve Size (mm)	Annulus Use Range Diameter (mm)[12]	Annulus Area (mm^2)[13]	Annulus Perimeter (mm)[13]
PRT-23	23	19–21	277–346	60–66
PRT-25	25	21–23	338–415	66–73
PRT-27	27	23–25	405–491	72–79
PRT-29	29	25–27	479–573	79–85

Information contained herein for **DISTRIBUTION outside of the U.S. ONLY.**
Always check the regulatory status for the device in your region.

FLEXNAV DELIVERY SYSTEM

Catalog Number	Equivalent Integrated Sheath Diameter (F)[1]	Outer Diameter (mm)[1]	Integrated Sheath Working Length (cm)[1]	Working Length (cm)[1]	Vascular Access Diameter (mm)[1]
FNAV-DS-SM	14	6.0	30	107	≥ 5.0
FNAV-DS-LG	15	6.3	30	107	≥ 5.5

Information contained herein for **DISTRIBUTION outside of the U.S. ONLY.**
Always check the regulatory status for the device in your region.

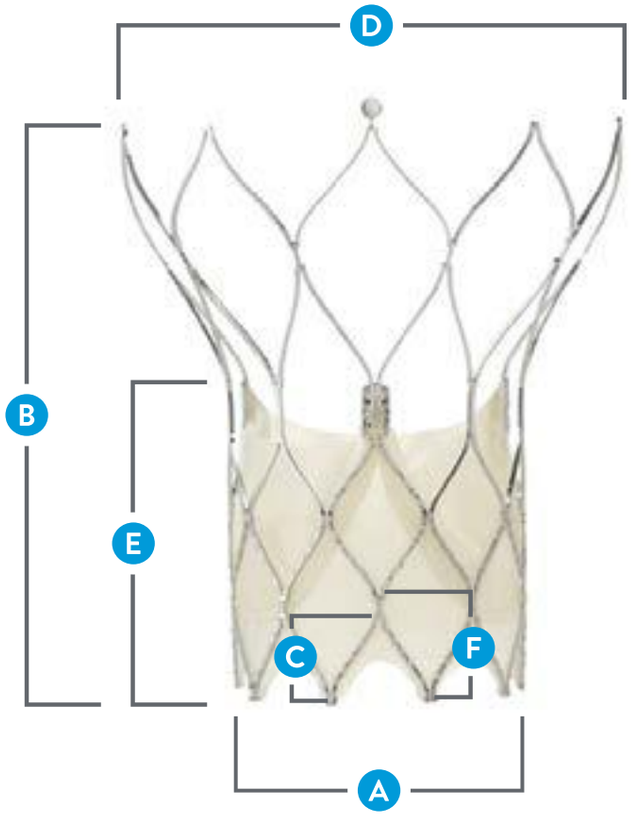
FLEXNAV LOADING SYSTEM

Catalog Number	
FNAV-LS-SM	The FlexNav™ loading system facilitates valve preparation/loading onto the FlexNav™ delivery system. The loading system includes a loading funnel, loading base, base insert, loading tube, and leaflet tester.
FNAV-LS-LG	

PORTICO TRANSCATHETER AORTIC VALVE SPECIFICATIONS

INDICATIONS FOR USE

The Portico™ valve is indicated for transcatheter delivery in patients with symptomatic severe native aortic stenosis who are considered high or extreme surgical risk.



A SIZING[14]	23 mm	25 mm	27 mm	29 mm
Annulus Use Range Diameter (mm)	19–21	21–23	23–25	25–27
Annulus Area (mm^2)	277–346	338–415	405–491	479–573
Annulus Perimeter (mm)	60–66	66–73	72–79	79–85
Ascending Aorta Diameter (mm)	26–36	28–38	30–40	32–42
Minimum Vessel Diameter (mm)	≥ 5.0	≥ 5.0	≥ 5.5	≥ 5.5
Cuff Sealing Zone (mm)	9	9	10	10
Implant Target Depth Below Annulus (mm)[14]	3	3	3	3

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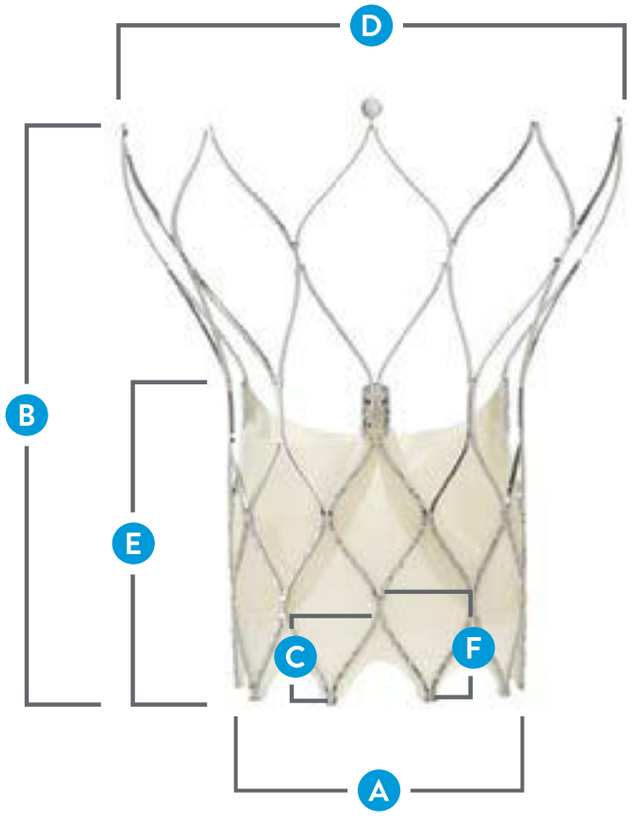
PORTICO TRANSCATHETER AORTIC VALVE SPECIFICATIONS

INDICATIONS FOR USE

The Portico™ valve is indicated for transcatheter delivery in patients with symptomatic severe native aortic stenosis who are considered high or extreme surgical risk.



	VALVE[14]	23 mm	25 mm	27 mm	29 mm
B	**Stent Height* (mm)**	50	53	49	50
C	**Ventricular Half-cell Height* (mm)**	7	7	8	8
D	**Stent Aortic Diameter* (mm)**	39	41	42	44
E	**Valve Tissue Height* (mm)**	26	28	28	29
F	**Inner Cuff Height* (mm)**	9	9	10	10

*Dimensions at fully expanded and unconstrained stent.

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PORTICO TRANSCATHETER AORTIC VALVE SPECIFICATIONS

INDICATIONS FOR USE

The Portico™ valve is indicated for transcatheter delivery in patients with symptomatic severe native aortic stenosis who are considered high or extreme surgical risk.

MATERIALS, PREPARATION, STORAGE & SHELF LIFE[14]

Valve Leaflet Material	Bovine Pericardium
Inner Cuff Material	Porcine Pericardium
Stent	Self-expanding nitinol
Tissue Anticalcification	Linx™ Anticalcification Treatment
Valve Preparation	Simple two short 10-second rinses in sterile isotonic saline at room temperature[1]
Storage Solution	Formaldehyde[1]
Storage Temperature	5°C–25°C (41°F–77°F)[1]
Shelf Life	Portico Valve[15,17] — 2 Years

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PORTICO TRANSCATHETER AORTIC VALVE SPECIFICATIONS

INDICATIONS FOR USE

The Portico™ valve is indicated for transcatheter delivery in patients with symptomatic severe native aortic stenosis who are considered high or extreme surgical risk.

VALVE PACKAGING AND STORAGE[1]

The valve is supplied in a jar containing formaldehyde storage solution. The jar has a screw cap closure and tamper-evident seal. The valve is supplied on a disposable holder. The contents of the jar are sterile and must be handled aseptically to prevent contamination. Store the valve in the upright position.

CAUTION: Do not use the valve without thoroughly rinsing as directed.

CAUTION: Do not use the valve if the shipping temperature indicator on the product package has turned red, or if the valve has been improperly stored in temperature conditions outside of the 5°C–25°C (41°F–77°F) range.

MAGNETIC RESONANCE (MR) SAFETY[1]

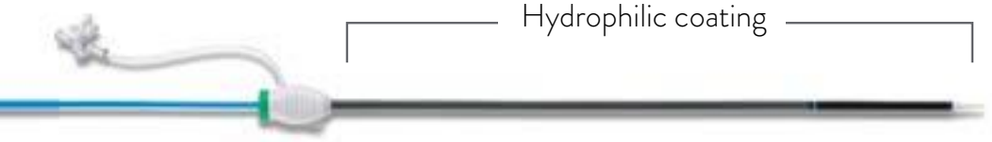
Non-clinical testing has demonstrated Portico™ transcatheter aortic heart valves are MR Conditional. Patients can safely be scanned immediately after implantation under the following conditions:

- Static magnetic field of 1.5 Tesla (1.5 T) or 3.0 Tesla (3.0 T)
- Maximum spatial gradient magnetic field of less than or equal to 3,000 gauss/cm (30 T/m)
- Normal Operating Mode: Maximum whole-body specific absorption rate of:
  - 2.0 W/kg for 15 minutes of scanning in Normal Operating Mode at 1.5 T
  - 2.0 W/kg for 15 minutes of scanning in Normal Operating Mode at 3.0 T

FLEXNAV DELIVERY SYSTEM/LOADING SYSTEM SPECIFICATIONS

INDICATIONS FOR USE

The FlexNav™ delivery system is indicated for transfemoral or subclavian/axillary delivery of the Portico™ valve.
The delivery system is indicated for insertion into the vessel with or without an arterial introducer sheath.
The FlexNav™ loading system is indicated for loading the Portico valve in the FlexNav delivery system.



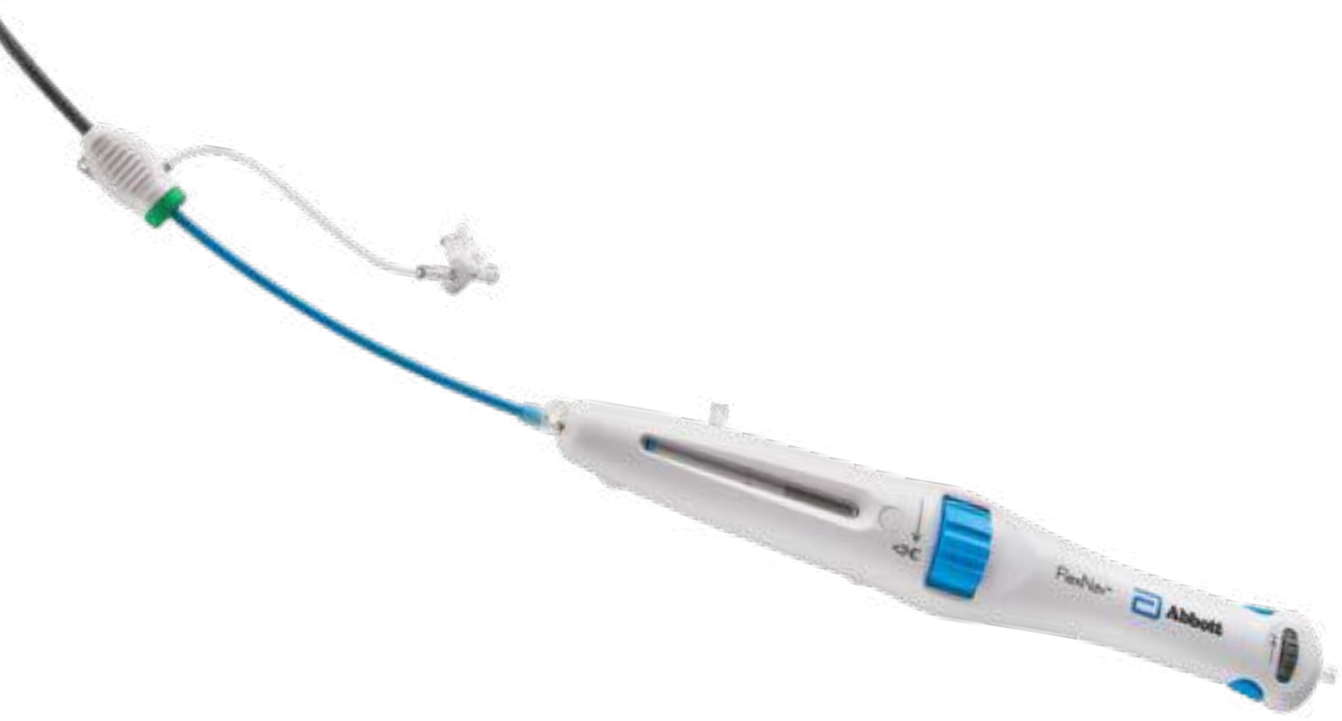
DELIVERY SYSTEM[14]	23 mm	25 mm	27 mm	29 mm
Guidewire Compatibility	0.035 inch compatible			
Outer Diameter - Distal End (mm)	SM 6.0		LG 6.3	
Vascular Access Diameter (mm)	≥ 5.0		≥ 5.5	
Working Length (cm)	107			
Hydrophilic Coating Length (mm)	354			
Capsule Length (mm)	83			
Integrated Sheath Length (mm)	251			
Nosecone Length (mm)	20			

FLEXNAV DELIVERY SYSTEM/LOADING SYSTEM SPECIFICATIONS

INDICATIONS FOR USE

The FlexNav™ delivery system is indicated for transfemoral or subclavian/axillary delivery of the Portico™ valve.
The delivery system is indicated for insertion into the vessel with or without an arterial introducer sheath.

The FlexNav™ loading system is indicated for loading the Portico valve in the FlexNav delivery system.



Information contained herein for **DISTRIBUTION outside of the U.S. ONLY.**
Always check the regulatory status for the device in your region.

SHELF LIFE

FlexNav Delivery System[15]	2 years
FlexNav Loading System[15]	2 years
Ultimum™ EV Introducer[16]	3 years

DELIVERY SYSTEM/LOADING SYSTEM PACKAGING AND STORAGE[1]

The delivery system and loading system are sterilized with ethylene oxide gas. The delivery system is supplied in a tray within an outer pouch.

The loading system is supplied in a double-barrier tray. The inner delivery system/loading system trays are supplied sterile provided the outer pouch/tray packaging is not opened or damaged.

DELIVERABILITY REDEFINED. TAVI REIMAGINED.
EXPERIENCE REMARKABLE DELIVERABILITY

PORTICO™ WITH FLEXNAV™ TAVI SYSTEM

References: 1. Portico IFU. **2.** Abbott Data on File. 90368819. **3.** Abbott Data on File. 90346620. **4.** Makkar RR, Cheng W, Waksman R, et al. Self-expanding intra-annular versus commercially available transcatheter heart valves in high and extreme risk patients with severe aortic stenosis (PORTICO IDE): a randomised, controlled, non-inferiority trial. *Lancet*. 2020;396(10252):669-683. **5.** Fontana GP, Bedogni F, Groh M, et al. Safety Profile of an Intra-Annular Self-Expanding Transcatheter Aortic Valve and Next-Generation Low-Profile Delivery System. J *Am Coll Cardiol Intv* 2020;13:2467 -78. **6.** Maisano F, Worthley S, Rodés-Cabau J, 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(8):886-893. **7.** Sondergaard L, Rodés-Cabau J, Linke AHP, et al. Transcatheter Aortic Valve Replacement With a Repositionable Self-Expanding Prosthesis. *Journal of the American College of Cardiology*. 2018;72(23):2859–67 **8.** Abbott, Data on File **9.** Manoharan G, Van Mieghem NM, Windecker S, 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(22):2326–2334. **10.** Wendler O, Schymik G, Treede H, 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.* 2017;135(12):1123-1132. **11.** Wendler O, Schymik G, Treede H, et al. SOURCE 3: 1-year outcomes post-transcatheter aortic valve implantation using the latest generation of the balloon-expandable transcatheter heart valve. *Eur. Heart J. 2017;38(36):2717-2726.* **12.** Abbott Data on File. 90078060. **13.** Abbott Data on File. 90432050. **14.** Abbott Data on File. 90432050/90465559. **15.** Shelf-Life Statement: Valve, Delivery System, and Loading System. Abbott Data on file.90434228/90434239. **16.** Ultimum DV report 90143910.

Information contained herein for **DISTRIBUTION outside of the U.S. ONLY.**
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CAUTION: This product is intended for use by or under the direction of a physician. Prior to use, reference the Instructions for Use, inside the product carton (when available) or at eifu.abbottvascular.com or at medical.abbott/manuals for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events.

Illustrations are artist's representations only and should not be considered as engineering drawings or photographs. Photo(s) on file at Abbott.

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PORTICO™

Transcatheter Aortic Heart Valve Implantation System

INDICATIONS FOR USE

The Portico™ transcatheter aortic heart valve is indicated for transcatheter delivery in patients with symptomatic severe native aortic stenosis who are considered high surgical risk.

SIZING[1]		23 mm	25 mm	27 mm	29 mm
Annulus Range (mm)		19–21	21–23	23–25	25–27
Area (mm^2)		277–346	338–415	405–491	479–573
Perimeter (mm)		60–66	66–73	72–79	79–85
Ascending Aorta Diameter (mm)		26–36	28–38	30–40	32–42
Minimum Vessel Diameter		≥ 6.0 mm (18 F)	≥ 6.0 mm (18 F)	≥ 6.5 mm (19 F)	≥ 6.5 mm (19 F)
Cuff Sealing Zone (mm)		9	9	10	10
Landing Zone (mm)		1–9	1–9	1–10	1–10
Implant Target or "Nominal" Depth Below Annulus (mm)		3	3	3	3
VALVE[1]					
Stent Height (mm)		50	53	49	50
Stent Width at Top* (mm)		39	41	42	44
Commissure Attachment Height (mm)		26	28	28	29
Valve Leaflets		Bovine Pericardium			
Inner Cuff Height		9 mm		10 mm	
Inner Cuff Material		Porcine Pericardium			
Stent		Self-expanding Nitinol			
Tissue Anticalcification		Linx™ Anticalcification Treatment			
Valve Preparation		Simple two short 10-second rinses in sterile isotonic saline at room temperature[2]			
Storage Solution		Formaldehyde[2]			
Storage Temperature		5°C–25°C (41°F–77°F)[2]			
Shelf Life:	Portico Transcatheter Aortic Heart Valve[3] Portico Delivery System[3] Portico Valve Loading System[3] Ultimum™ EV Introducer[4]	2 years 4 years 2 years 3 years			
DELIVERY SYSTEM[1]					
Guidewire Compatibility		0.035 inch compatible			
Outer Diameter — Distal End		18 F/6.0 mm		19 F/6.33 mm	
Outer Diameter — Proximal End		13 F/4.33 mm			
Vascular Access Diameter (mm)		≥ 6.0		≥ 6.5	
Working Length		110 cm			

*Dimensions at fully expanded and unconstrained stent.

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PACKAGING AND STORAGE[2]

The valve is supplied in a jar containing formaldehyde storage solution. The jar has a screw cap closure and tamper-evident seal. The valve is supplied on a disposable holder. The contents of the jar are sterile and must be handled aseptically to prevent contamination. Store the valve in the upright position.

CAUTION: Do not use the valve without thoroughly rinsing as directed.

CAUTION: Do not use the valve if the shipping temperature indicator on the product package has turned red, or if the valve has been improperly stored in temperature conditions outside of the 5°C–25°C (41°F–77°F) range.

MAGNETIC RESONANCE (MR) SAFETY[2]

Non-clinical testing has demonstrated Portico™ transcatheter aortic heart valves are MR Conditional. Patients can safely be scanned immediately after implantation under the following conditions:

- Static magnetic field of 1.5 Tesla (1.5 T) or 3.0 Tesla (3.0 T)
- Maximum spatial gradient magnetic field of less than or equal to 3,000 gauss/cm (30 T/m)
- Normal Operating Mode: Maximum whole-body specific absorption rate of:
  - 2.0 W/kg for 15 minutes of scanning in Normal Operating Mode at 1.5 T
  - 2.0 W/kg for 15 minutes of scanning in Normal Operating Mode at 3.0 T

REFERENCE

1. Abbott. Data on File. 90432050.
2. Portico IFU.
3. Portico Shelf-Life Statement: Valve, Delivery System, and Loading System.
4. Portico Shelf-Life Statement: Ultimum EV Introducer.

CAUTION: This product is intended for use by or under the direction of a physician. Prior to use, reference the Instructions for Use, inside the product carton (when available) or at eifu.abbottvascular.com or at medical.abbott/manuals for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events. Information contained herein for **DISTRIBUTION outside of the U.S. ONLY**. Check the regulatory status of the device in areas where CE marking is not the regulation in force.

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www.cardiovascular.abbott

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ST. JUDE MEDICAL

SJM Declaration of Conformity
Portico™ Transcatheter Aortic Heart Valve System

St. Jude Medical (SJM) hereby declares that the following SJM facilities and products conform to the applicable provisions of Annex II of the Medical Device Directive (MDD) 93/42/EEC, as amended by 2007/47/EC; and EU Regulation 722/2012. All supporting documentation is retained under the premises of SJM. We declare no application has been lodged with any other notified body for the same products. This declaration is issued under the sole responsibility of the manufacturer. This declaration supersedes any declaration issued previously for the same product(s).

Manufacturer Address:

St. Jude Medical
177 County Road B East
St. Paul, MN 55117 USA

European Representative:

St. Jude Medical Coordination Center BVBA
The Corporate Village
Da Vincilaan 11 Box F1
1935 Zaventem, Belgium

Product Type:

Transcatheter Heart Valve and Delivery Systems

Product Name(s):

Portico™ Transcatheter Aortic Heart Valve
Portico™ Transcatheter Delivery System
Portico™ Transcatheter ALT Delivery System
FlexNav™ Transcatheter Delivery System

Model Number(s):

Heart Valve	*Delivery System*
PRT-23	*PRT-DS-TF-18F*
PRT-25	*PRT-DS-ALT-18F* *FNAV-DS-SM*
PRT-27	*PRT-DS-TF-19F*
PRT-29	*PRT-DS-ALT-19F* *FNAV-DS-LG*

Classification:

Class III per Annex IX, Rule 17 and Rule 6

GMDN Code(s):

60245 (Transcatheter Heart Valve)
63283 (Delivery System)

Original CE Mark Date:

2012 November 16

DE Certificate No and expiration date:

Certificate No: CE 585003
Expiration Date: 2022 Nov 15

Signature:

Jeff Sturm
Associate Director, Regulatory Affairs

7 FEB 2020
Issue Date

ST. JUDE MEDICAL

SJM Declaration of Conformity
Portico™ Transcatheter Aortic Heart Valve System

FQA Certificate No and expiration date:	Certificate No: CE 578287 Expiration Date: 2024 May 26
Applicable Quality System Standards:	ISO 13485:2016
Notified Body:	BSI Group The Netherlands B.V. Say Building John M. Keynesplein 9 1066 EP Amsterdam Netherlands
Notified Body Number:	2797
Manufacturing Facilities:	St. Jude Medical 177 County Road B East St. Paul, MN 55117 St. Jude Medical 14901 DeVeau Place Minnetonka, MN 55345 St. Jude Medical Costa Rica Ltda. Edificio #44 Calle 0, Ave. 2 Zona Franca El Coyol, Alajuela Costa Rica

Signature:

Jeff Sturm
Associate Director, Regulatory Affairs

7 FEB 2020
Issue Date

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 578287**

Issued To: **St. Jude Medical**
177 County Road B East
St. Paul
Minnesota
55117
USA

In respect of:

Design and manufacture of Sterile Mechanical and Tissue Heart Valves, Transcatheter Heart Valves, Valved Grafts, Annuloplasty Rings and Sterile and Non-Sterile Related Accessories.

Those aspects of Annex II related to securing and maintaining sterility in the manufacture of valve related accessories.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2012-01-30** Date: **2020-06-19** Expiry Date: **2024-05-26**

...making excellence a habit.™

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 578287

Issued To:

St. Jude Medical
177 County Road B East
St. Paul
Minnesota
55117
USA

Number	Device Name	Intended Purpose per IFU
Class III		
---	Masters Series Mechanical Heart Valve – Mechanical Heart Valves	See CE 578290
	Masters Series Mechanical Heart Valve with Expanded Polyester Sewing Cuff – Mechanical Heart Valves	
	Masters Series Mechanical Heart Valve with PTFE Sewing Cuff – Mechanical Heart Valves	
	Masters Series Mechanical Heart Valve with Expanded PTFE Sewing Cuff – Mechanical Heart Valves	
	Masters Series Mechanical Heart Valve with Hemodynamic Plus (HP) Sewing Cuff – Mechanical Heart Valves	
	Masters Series Mechanical Heart Valve with Expanded Hemodynamic Plus (HP) Sewing Cuff – Mechanical Heart Valves	
	Regent Heart Valve – Mechanical Heart Valves	
	Regent Heart Valve with FlexCuff – Mechanical Heart Valves	

First Issued: **2012-01-30** Date: **2020-06-19** Expiry Date: **2024-05-26**

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 578287

Issued To:

St. Jude Medical
177 County Road B East
St. Paul
Minnesota
55117
USA

Number	Device Name	Intended Purpose per IFU
Class III		
---	Masters HP Valved Graft with Gelweave Valsalva Technology (VAVGJ) – Valved Grafts	See CE 578291
---	Masters Valved Graft with Hemashield Graft Technology (CAVGJ) – Valved Grafts	See CE 578292
---	Tailor Annuloplasty Ring and Tailor Annuloplasty Band – Annuloplasty Rings	See CE 578289
	Rigid Saddle Ring Annuloplasty Ring – Annuloplasty Rings	
---	Seguin Annuloplasty Ring – Annuloplasty rings	See CE 578288
---	Portico Transcatheter Aortic Heart Valve System – Transcatheter Heart Valves	See CE 585003
---	Trifecta and Trifecta GT – Tissue Heart Valves	See CE 617862
---	Biocor, Epic and Epic Supra – Tissue Heart Valves	See CE 617865

First Issued: **2012-01-30** Date: **2020-06-19** Expiry Date: **2024-05-26**

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 578287

Issued To:

St. Jude Medical
177 County Road B East
St. Paul
Minnesota
55117
USA

Number	Device Name	Intended Purpose per IFU
Class IIa		
MD0106, MDS7006	Mechanical Heart Valve Leaflet Tester – Related Accessories	---
MD0106	Masters Series Mechanical Heart Valve Replacement Holder/Rotators – Related Accessories	---
	Masters Series Hemodynamic Plus (HP) Mechanical Heart Valve Replacement Holder/Rotators – Related Accessories	
	Regent Mechanical Heart Valve Replacement Holder/Rotators – Related Accessories	
	Rigid Saddle Ring Annuloplasty Sizer Set – Related Accessories	
	Tailor Annuloplasty Ring Sizer Set– Related Accessories	
	Tailor Ring Robotic Sizer Set – Related Accessories	
	Seguin Annuloplasty Ring Sizer Set – Related Accessories	
	Mechanical Heart Valve Sizer – Related Accessories	

First Issued: **2012-01-30** Date: **2020-06-19** Expiry Date: **2024-05-26**

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 578287

Issued To:

St. Jude Medical
177 County Road B East
St. Paul
Minnesota
55117
USA

Number	Device Name	Intended Purpose per IFU
Class IIa		
MD0106	Regent Mechanical Heart Valve Sizer Set – Related Accessories	---
	Trifecta Valve Series Sizer Set – Related Accessories	
	Bioprosthetic Heart Valve Sizer Set – Related Accessories	

First Issued: **2012-01-30** Date: **2020-06-19** Expiry Date: **2024-05-26**

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 578287

Issued To:

St. Jude Medical
177 County Road B East
St. Paul
Minnesota
55117
USA

Number	Device Name	Intended Purpose per IFU
Class Is		
MD0106 MDS7006	Portico Valve loading System	---
MD0106 MDS7006	FlexNav loading System	---

First Issued: **2012-01-30** Date: **2020-06-19** Expiry Date: **2024-05-26**

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 578287**
Date:	**2020-06-19**
Issued To:	**St. Jude Medical** **177 County Road B East** **St. Paul** **Minnesota** **55117** **USA**

Subcontractor:	**Service(s) supplied**
Abbott Medical 5050 Nathan Lane North Plymouth Minnesota 55442 USA	**Manufacture** **Microbiology Service**
Abbyland PorkPak Inc. 539 North Meridian Street Curtiss Wisconsin 54422 USA	**Animal Tissues / Derivatives**
Agrodanieli Indústria e Comércio Ltda Rodivia 463, KM 14,5 Disrito Industrial Vila Langaro Rio Grande do Sul Brasil	**Animal Tissues / Derivatives**

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

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Certificate No:	**CE 578287**
Date:	**2020-06-19**
Issued To:	**St. Jude Medical** **177 County Road B East** **St. Paul** **Minnesota** **55117** **USA**

Subcontractor:	**Service(s) supplied**
Agropecuária Bolson Ltda. (Bolson) Rua Vereador Waldomiro Franco de Souza, S/N - Zona Suburbana Toledo Paraná Brasil	**Animal Tissues / Derivatives**
Bierig Brothers Inc. 3539 Reilly Ct. Vineland New Jersey 08360 USA	**Animal Tissues / Derivatives**
BRF - Brasil Foods S.A. Rua Senador Atilio Fontana, 86, Concordia/SC Brasil	**Animal Tissues / Derivatives**

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

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Certificate No:	**CE 578287**
Date:	**2020-06-19**
Issued To:	**St. Jude Medical** **177 County Road B East** **St. Paul** **Minnesota** **55117** **USA**

Subcontractor:	**Service(s) supplied**
BRF Brasil Foods S/A Herval D'Oeste Facility (HDO) Avenida Presidente Castelo Branco 141 Centro Herval D'Oeste Santa Caterina 89610 Brasil	**Animal Tissues / Derivatives**
Bugio Agropecuaria LTDA Rodovia SC 283 KM 08 – Linha Marcom Estrada para Chapecó Chapecó/Seara Santa Caterina Brasil	**Animal Tissues / Derivatives**
Frigoestrela S.A. Estrada Vicinal Romão Lopes Martins, S/N - KM 0+700M, Jardim Marabá, Tupã/SP Brasil	**Animal Tissues / Derivatives**

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

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Certificate No:	**CE 578287**
Date:	**2020-06-19**
Issued To:	**St. Jude Medical** **177 County Road B East** **St. Paul** **Minnesota** **55117** **USA**

Subcontractor:	**Service(s) supplied**
Frigorifico Miolar Ltda Estrada para Fazenda Mazurana S/N, Dois Vizinhos/PR Brasil	**Animal Tissues / Derivatives**
Frimesa Cooperativa Central Rua Bahia, 159, Medianeira/PR Brasil	**Animal Tissues / Derivatives**
Hereaus Medical Components, LLC 5030 Centerville Road St Paul Minnesota 55127 USA	**Manufacture**
InterVascular SAS Z.I. Athélia 1 13705 La Ciotat Cedex France	**Manufacture**

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 578287**
Date:	**2020-06-19**
Issued To:	**St. Jude Medical** **177 County Road B East** **St. Paul** **Minnesota** **55117** **USA**

Subcontractor:	**Service(s) supplied**
Irmãos do Valle (IDV) Rodovia BR 116, KM 116 Caixa Postal 04 - Bairro: Campo Alto - Santa Cecilia Santa Catarina Brasil	**Animal Tissues / Derivatives**
Isomedix Operations, Inc. 380 90th Avenue NW Minneapolis Minnesota 55433 USA	**ETO Sterilization**
JBS Aves Ltda Rua João Andriollo, 1167, Ana Rech Caxias do Sul/RS Brasil	**Animal Tissues / Derivatives**

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 578287**
Date:	**2020-06-19**
Issued To:	**St. Jude Medical** **177 County Road B East** **St. Paul** **Minnesota** **55117** **USA**

Subcontractor:	**Service(s) supplied**
JBS S.A. Parque Industrial S/N Distrito Industrial, LINS/SP Brasil	**Animal Tissues / Derivatives**
JBS S.A. Rodovia, GO 164, Km 167 S/N, Zona Rural, Mozarlândia/GO Brasil	**Animal Tissues / Derivatives**
JBS S.A. Rua Principal S/N, Vila Miisa, Ituiutaba/MG Brasil	**Animal Tissues / Derivatives**
JBS S.A. Facility I Av. Duque de Caxias 7255 Vila Nova Campo Grande/MS Brasil	**Animal Tissues / Derivatives**

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 578287**
Date:	**2020-06-19**
Issued To:	**St. Jude Medical** **177 County Road B East** **St. Paul** **Minnesota** **55117** **USA**

Subcontractor:	**Service(s) supplied**
Mac Frios Rod. Antônio de Paiva Cantelmo, PR 566- KM 02, Zona Rural, Francisco Beltrão/PR Brasil	**Animal Tissues / Derivatives**
Marcho Farms Inc. 519 Allentown Road Franconia Pennsylvania 18924 USA	**Animal Tissues / Derivatives**
Midwest Sterilization Corporation 1204 Lenco Avenue Jackson Missouri 63755 USA	**ETO Sterilization**

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 578287**
Date:	**2020-06-19**
Issued To:	**St. Jude Medical** **177 County Road B East** **St. Paul** **Minnesota** **55117** **USA**

Subcontractor:	**Service(s) supplied**
Oakey Abattoir Lot 1, Oakey Connection Road, Oakey QLD 4401 Australia	**Animal Tissues / Derivatives**
P&N Packaging Inc. 11627 Route 187 Wyalusing Pennsylvania 18853 USA	**Animal Tissues / Derivatives**
Phillips-Medisize, LLC 705 Wisconsin Drive New Richmond Wisconsin 54017 USA	**Manufacture**

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 578287**
Date:	**2020-06-19**
Issued To:	**St. Jude Medical** **177 County Road B East** **St. Paul** **Minnesota** **55117** **USA**

Subcontractor:	**Service(s) supplied**
POCO Graphite, Inc. an Entegris Company 300 Old Greenwood Road Decatur Texas 76234 USA	**Crucial Supplier**
Quality Central de Esterilização Estrada Celso Charur, i23 Aracoiaba de Serra Sao Paulo 18190-000 Brasil	**ETO Sterilization**
Rio Branco Alimentos S.A. (Pif Paf) BR 365 Km 455, Patrocínio/MG Brasil	**Animal Tissues / Derivatives**

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 578287**
Date:	**2020-06-19**
Issued To:	**St. Jude Medical** **177 County Road B East** **St. Paul** **Minnesota** **55117** **USA**

Subcontractor:	**Service(s) supplied**
Seara Alimentos Ltda Rua Tranquilo Damo, 209 -Santo Antonio, Frederico Westphalen/RS Brasil	**Animal Tissues / Derivatives**
Sioux-Preme Packing Company 4241 U.S. 75 Ave Sioux Center Iowa 51250 USA	**Animal Tissues / Derivatives**
St. Jude Medical 14901 DeVeau Place Minnetonka Minnesota 55345-2126 USA	**Manufacture**

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 578287**
Date:	**2020-06-19**
Issued To:	**St. Jude Medical** **177 County Road B East** **St. Paul** **Minnesota** **55117** **USA**

Subcontractor:	**Service(s) supplied**
St. Jude Medical 177 County Road B East St. Paul Minnesota 55117 USA	**Final Inspection** **Labelling** **Manufacture** **Moist Heat Sterilization** **Packaging**
St. Jude Medical Brasil Ltda. Rua Professor Jose Vierra de Mendonca 1301 Bairro Engenho Nogueira Pampulha, Belo Horizonte Minas Gerais 31.310-026 Brasil	**Manufacture**
St. Jude Medical Coordination Center BVBA The Corporate Village Da Vincilaan 11 Box F1 1935 Zaventem Belgium	**EU Representative** **Labelling** **Packaging**

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 578287**
Date:	**2020-06-19**
Issued To:	**St. Jude Medical** **177 County Road B East** **St. Paul** **Minnesota** **55117** **USA**

Subcontractor:	**Service(s) supplied**
St. Jude Medical Costa Rica Ltda. Edificio #44 Calle 0, Ave. 2 Zona Franca Coyol El Coyol, Alajuela Costa Rica	**Manufacture**
St. Jude Medical PR LLC Caguas West Industrial Park Lot 20 Caguas 00725 Puerto Rico	**Final Inspection** **Manufacture** **Moist Heat Sterilization**
St. Jude Medical Puerto Rico LLC Lot A Interior - #2 Rd Km. 67.5 Santana Industrial Park Arecibo Puerto Rico 00612 USA	**ETO Sterilization**

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 578287**
Date:	**2020-06-19**
Issued To:	**St. Jude Medical** **177 County Road B East** **St. Paul** **Minnesota** **55117** **USA**

Subcontractor:	**Service(s) supplied**
Sterigenics Costa Rica S.R.L. Zona Franca Propark Calle Principal, Edificio 10, El Coyol Alajuela 20101 Costa Rica	**ETO Sterilization**
Sterigenics US, LLC 5725 West Harold Gatty Drive Salt Lake City Utah 84116 USA	**ETO Sterilization**
Steris Isomedix Puerto Rico LLC State Road 690 KM 1.7 Barrio Sabana Hoyos Vega Alta 00692 Puerto Rico USA	**Gamma Irradiation**

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 578287**
Date:	**2020-06-19**
Issued To:	**St. Jude Medical** **177 County Road B East** **St. Paul** **Minnesota** **55117** **USA**

Subcontractor:	**Service(s) supplied**
Teys Australia Southern, Tamworth Phoenix street Tamworth, NSW 2340 Australia	**Animal Tissues / Derivatives**
Vascutek Limited Newmains Avenue Inchinnan PA4 9RR United Kingdom	**Animal Tissues / Derivatives** **Manufacture**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 578287**

Date: **2020-06-19**

Issued To: **St. Jude Medical**
177 County Road B East
St. Paul
Minnesota
55117
USA

Date	Reference Number	Action
30 January 2012	7727627	First issue of mirror certificate to CE 544668.
8 June 2012	7816634	Addition of significant subcontractor for sterilization to St Jude Medical Puerto Rico LLC for VAVGJ devices.
16 November 2012	7910273	Transcatheter valves added to the scope. Addition of St Jude Medical (Minnetonka), St Jude Medical (Maple Grove), Marcho Farms and Abbyland PorkPak to the list of subcontractors.
13 December 2012	7930677	Update to subcontractor address St Jude Medical PR LLC.
16 January 2013	7943381	St Jude Medical (Costa Rica) added to the list of subcontractors.
18 April 2013	7984806	St Jude Medical (Maple Grove) removed from the list of subcontractors.
10 November 2013	8071312	Addition of significant subcontractor InterVascular SAS (Maquet) La Ciotat France facility as a fabric supplier for SJM Mechanical Heart Valves, Valved Grafts and Annuloplasty Rings.
19 November 2014	8245105	Certificate renewal.
01 December 2014	8194269	Tissue valves and pericardial patches added to the scope (transferred from another Notified Body). St Jude Medical Brasil, Phillips Plastics and bovine porcine abattoirs added to the list of subcontractors.

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 578287**
Date: **2020-06-19**
Issued To: **St. Jude Medical**
177 County Road B East
St. Paul
Minnesota
55117
USA

Date	Reference Number	Action
16 March 2015	8297445	Addition of Packaging & Labelling to activities of St. Jude Medical Coordination Center BVBA.
08 July 2015	8288225	Addition of the US abattoir Greater Omaha Packaging Company as a Bovine Tissue Source for Trifecta™ Heart Valve. Removal of subcontractors STERIS Spartanburg and Maquet Cardiovascular.
03 August 2015	8351515	Addition of Brazilian abbatoirs Frigorifico K-Celet Alimentos, Primaz Frigorifico Ltda, and SBR Suinos Brazil Ltda as porcine cusps suppliers for the manufacture of the Biocor, Epic and Epic Supra Heart Valves.
07 December 2015	8433259	Addition of Sterigenics US, LLC, Willowbrook, IL as a significant subcontractor for ETO sterilization.
01 August 2016	8520657	JBS S.A. Facility I added as a bovine pericardium supplier.
23 January 2017	8632751	Removal of subcontractor W&G Marketing.
30 March 2017	8576083	Addition of Agropecuária Bolson Ltda., Irmãos do Valle and W&G Marketing Company as animal tissue suppliers.
4 September 2017	8693815	Addition of subcontractor Quality Central de Esterilização, Brasil as an alternate sterilizer for Biocor Pericardial Patch.
26 October 2017	8694458	Addition of Poco Graphite as crucial supplier and Sterigenics Costa Rica as EO sterilizer. Removal of Steris Minneapolis.
02 May 2018	8917138	Addition of Bierig Brothers Inc. and P&N Packaging Inc. as bovine pericardium suppliers for the Portico valve.

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 578287**
Date: **2020-06-19**
Issued To: **St. Jude Medical**
177 County Road B East
St. Paul
Minnesota
55117
USA

Date	Reference Number	Action
07 March 2019	7780704	Traceable to NB 0086.
07 May 2019	9752176	Addition of Sterigenics US, LLC, Salt Lake City, Utah USA as a significant subcontractor for ETO Sterilization.
03 December 2019	9688437	Addition of Isomedix Operations Inc. (Steris), Minneapolis USA as a significant subcontractor for ETO sterilization, following inadvertent deletion.
11 December 2019	9775758	Certificate Renewal. Removal of Pericardial Patches from the scope. Addition of product table. Removal of discontinued animal tissue suppliers: Greater Omaha Packaging Company, Frigorifico Argus Ltda, Frigorifico K-Celet Alimentos, Primaz Frigorifico Ltda and W&G Marketing Company. Addition of Abbott Medical Plymouth Site as a subcontractor for Manufacture. Addition of Midwest Sterilization Corporation as a subcontractor for ETO sterilization. Change subcontractor name 'SBR Suinos Brazil Ltda' to 'Agrodanieli Indústria e Comércio Ltda'. Additional minor alignments of subcontractor name and addresses with ISO certificates.

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 578287**

Date: **2020-06-19**

Issued To: **St. Jude Medical**
177 County Road B East
St. Paul
Minnesota
55117
USA

Date	Reference Number	Action
28 January 2020	3126325	Extension to scope to include class Is devices. Clarification to scope (sterile devices). Minor typo correction (Sioux Preme postal code). Removal of Sterigenics Willowbrook, IL USA. Addition of Microbiology Services to Abbott Medical, Plymouth, MN, USA.
Current	3220927	Addition of Bugio Agropecuaria LTDA as animal tissue supplier for the Biocor/Epic heart valves. Addition of BRF Brasil Foods S/A – Herval D'Oeste Facility (HDO) as an animal tissue supplier for the Trifecta and Biocor/Epic heart valves.

EC Design-Examination Certificate

Directive 93/42/EEC on Medical Devices, Annex II Section 4

No. **CE 585003**

Issued To: **St. Jude Medical**
177 County Road B East
St Paul
Minnesota
55117
USA

In respect of:

Portico™ Transcatheter Aortic Heart Valve System

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC Annex II Section 4 and Regulation 722/2012. The design conforms to the requirements of this directive and regulation. For marketing of these products an additional Annex II excluding Section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):

Stewart Brain, Head of Compliance & Risk - Medical Devices

First Issued: **2012-11-16** Date: **2017-11-15** Expiry Date: **2022-11-15**

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EC Design-Examination Certificate

Supplementary Information to CE 585003

Issued To:

St. Jude Medical
177 County Road B East
St Paul
Minnesota
55117
USA

Size/Access	Heart Valve	Delivery System	Loading System
23mm / Transfemoral	PRT-23	PRT-DS-TF-18F	PRT-LS-TF/ALT-18F
25mm / Transfemoral	PRT-25		
27mm / Transfemoral	PRT-27	PRT-DS-TF-19F	PRT-LS-TF/ALT-19F
29mm / Transfemoral	PRT-29		

First Issued: **2012-11-16** Date: **2017-11-15** Expiry Date: **2022-11-15**

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EC Design-Examination Certificate

Supplementary Information to CE 585003

Issued To:

St. Jude Medical
177 County Road B East
St Paul
Minnesota
55117
USA

Certificate History

Date	Reference Number	Action
16 November 2012	10134049	First Issue.
16 January 2013	10139233	Valve manufacturing moved to St. Jude Medical Costa Rica.
18 April 2013	10141298	Stent manufacturing moved to the St. Paul facility (177 County Road B East).
14 May 2013	10141486	Valve shelf life extended to 12 months.
11 December 2013	10143493	Line extension to include 25mm valve. Introduction of electronic IFU for the valve. Introduced reference to Regulation (EU) 722/2012.
07 April 2014	10146232	Delivery system and loading system changes: design/material modifications, shelf life extension to 12 months, introduction of electronic IFU and update of the catalogue numbers.
18 May 2015	10154403	Shelf life of delivery system and loading system extended to 2 years.
25 August 2015	10156926	DuPont Tyvek Medical Transition Project update.
14 September 2015	10157250	Valve shelf life extended to 24 months.
15 September 2015	10146798	Line extension to include 27mm and 29mm valves and 19F delivery system and loading system.
01 February 2016	10160623	Addition of Sterigenics Willowbrook, IL as a sterilizer.

First Issued: **2012-11-16** Date: **2017-11-15** Expiry Date: **2022-11-15**

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EC Design-Examination Certificate

Supplementary Information to CE 585003

Issued To:

St. Jude Medical
177 County Road B East
St Paul
Minnesota
55117
USA

Date	Reference Number	Action
15 August 2016	10163673	Final assembly and packaging of delivery and loading systems moved to the Woodridge facility (177 County Road B East, St. Paul, USA).
12 September 2016	10165209	Valve shelf life extended to 24 months for sizes 27mm and 29mm.
04 December 2016	10167255	Portico Delivery Systems (PRT-DS-TF-18F, PRT-DS-TF-19F) shelf life extended to 4 years.
16 May 2017	10171081	Portico Delivery System Nosocone design change.
9 August 2017	8692515	18Fr and 19Fr Delivery Systems Lead Screw Stop Tab design change.
26 October 2017	8694459	Addition of Sterigenics Costa Rica as ETO sterilizer for the jar set assemblies.
Current	8795349	Certificate renewal

First Issued: **2012-11-16** Date: **2017-11-15** Expiry Date: **2022-11-15**

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Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

St. Jude Medical
177 County Road B East
St Paul
Minnesota
55117
USA

Holds Certificate No: **FM 558476**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

Design, development and Manufacture of and finished Mechanical Heart Valves, Tissue Heart Valves, Annuloplasty Rings, Valve and Annuloplasty Ring Sizer Sets, Mechanical Valve Leaflet Testers, Holder Rotators, Transcatheter Heart Valve Delivery and Loading Systems and related accessories along with manufacturing of intermediate components used in other medical devices.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2009-12-24
Latest Revision Date: 2020-01-13

Effective Date: 2020-02-29
Expiry Date: 2023-02-28

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Certificate No: **FM 558476**

Location	Registered Activities
St. Jude Medical 177 County Road B East St Paul Minnesota 55117 USA	Design, development and Manufacture of and finished Mechanical Heart Valves, Tissue Heart Valves, Annuloplasty Rings, Valve and Annuloplasty Ring Sizer Sets, Mechanical Valve Leaflet Testers, Holder Rotators, Transcatheter Heart Valve Delivery and Loading Systems and related accessories along with manufacturing of intermediate components used in other medical devices.
St. Jude Medical Brasil Ltda. Rua Professor Jose Vieira de Mendonca 1301 Bairro Engenho Nogueira Pampulha, Belo Horizonte Minas Gerais 31.310-026 Brasil	The Manufacture and final inspection of tissue made heart valves and tissue vascular prostheses.

Original Registration Date: 2009-12-24

Latest Revision Date: 2020-01-13

Effective Date: 2020-02-29

Expiry Date: 2023-02-28

CERTIFICATE

This is to certify that

SANTE INTERNATIONAL S.A.

Str. Mantuleasa nr. 33, Sector 2
023961 Bucuresti
Romania

has implemented and maintains a **Quality Management System**.

Scope:
Import, trade and storage of medical and laboratory equipment, disinfectants, laboratory reagents, cardiovascular surgery devices, service for medical and laboratory equipment. Consulting for state and private medical units.

Through an audit, documented in a report, it was verified that the management system fulfills the requirements of the following standard:

ISO 9001 : 2015

Certificate registration no.	497269 QM15
Valid from	2021-06-16
Valid until	2024-06-15
Date of certification	2021-06-16

DQS GmbH

Markus Bleher
Managing Director

Accredited Body: DQS GmbH, August-Schanz-Straße 21, 60433 Frankfurt am Main, Germany
Administrative Office: DQS Romania, Str. Bratului nr. 11, 020565 Bucharest - Romania

Annex to certificate
Registration No. 497269 QM15

SANTE INTERNATIONAL S.A.

Str. Mantuleasa nr. 33, Sector 2
023961 Bucuresti
Romania

Location	Scope
075906 **Sante International SA** **Sos. Mihai Bravu nr. 7, bl. P37-P37A, sector 2** **021303 Bucuresti** **Romania**	Import, trade and storage of medical and laboratory equipment, disinfectants, laboratory reagents, cardiovascular surgery devices. Consulting for state and private medical units.
497270 **Sante International SA** **Str. Pupitrului, nr. 81, sect. 3** **033036 Bucuresti** **Romania**	Storage of medical and laboratory equipment, disinfectants, laboratory reagents,cardiovascular surgery devices, service for medical and laboratory equipment. Consulting for state and private medical units.
31050285 **Sante International SA** **Calea Ghirodei, nr. 36** **300327 Timisoara** **Romania**	Trade of medical and laboratory equipment, disinfectants, laboratory reagents, cardiovascular surgery devices, service for medical and laboratory equipment. Consulting for state and private medical units.
31050284 **Sante International SA** **Calea Dorobantilor, nr. 111** **400609 Cluj-Napoca** **Romania**	Trade of medical and laboratory equipment, disinfectants, laboratory reagents, cardiovascular surgery devices, service for medical and laboratory equipment. Consulting for state and private medical units.
31050283 **Sante International SA** **Str. Lascar Catargi, nr. 37** **700107 Iasi** **Romania**	Trade of medical and laboratory equipment, disinfectants, laboratory reagents, cardiovascular surgery devices, service for medical and laboratory equipment. Consulting for state and private medical units.

This annex (edition:2021-06-16) is only valid in connection with the above-mentioned certificate.