



# DESIGNING THE FUTURE OF TAVI

TRANSFORMATIONAL DESIGN THAT DELIVERS UNPRECEDENTED OUTCOMES

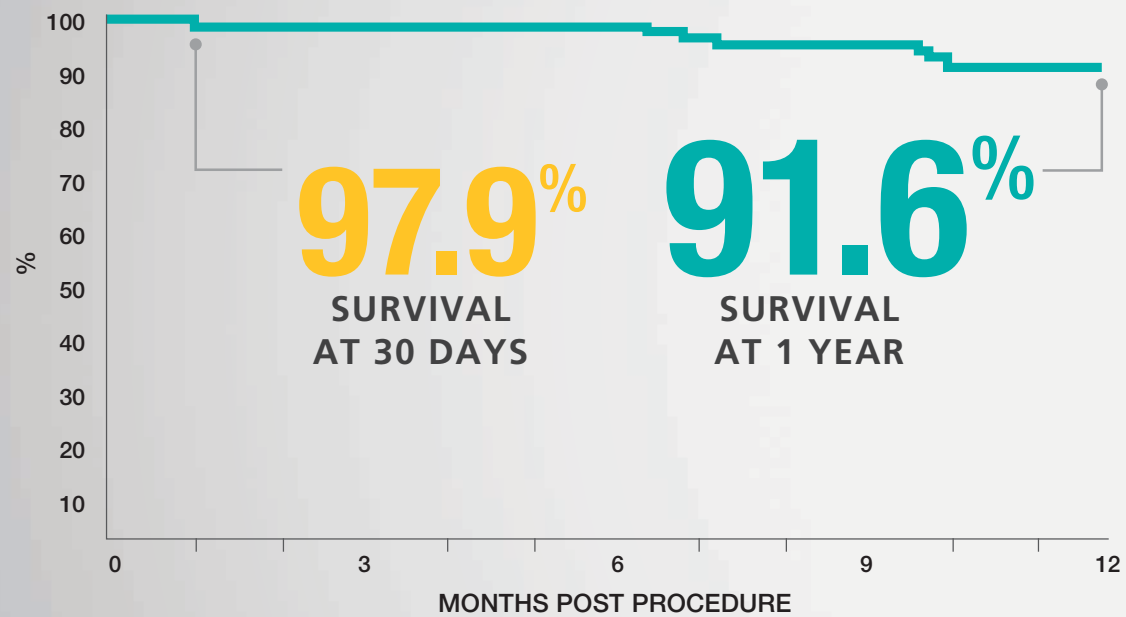


Edwards

# UNPRECEDENTED OUTCOMES CONTINUED THROUGH 1 YEAR

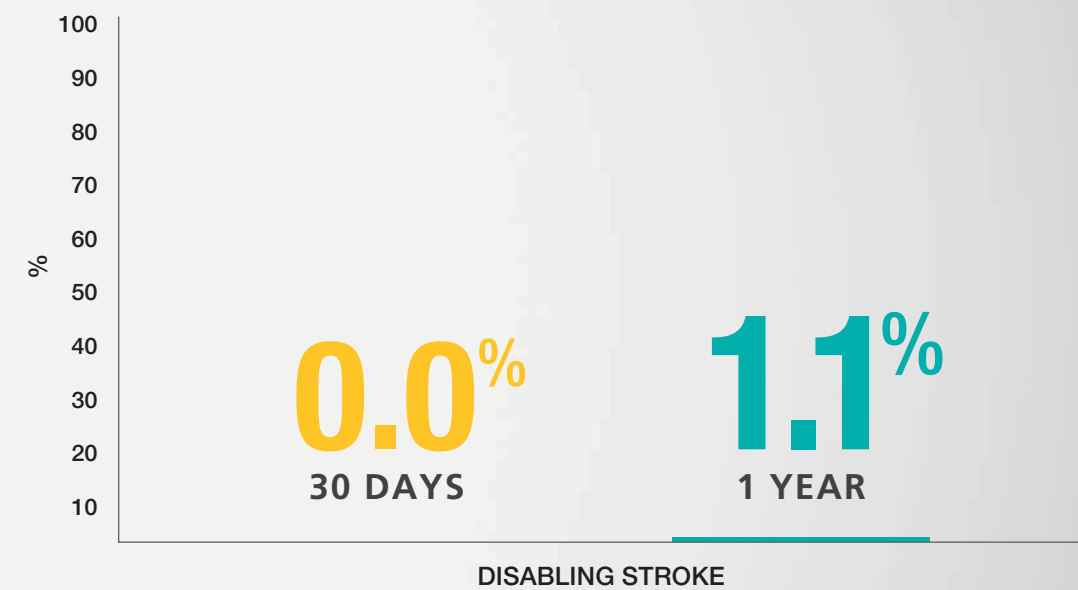
THE HIGHEST SURVIVAL EVER REPORTED  
IN A CLINICAL TRIAL AT 1 YEAR\*

TRANSFEMORAL COHORT



LOWEST RATE OF DISABLING STROKE  
AT 1 YEAR\*

TRANSFEMORAL COHORT



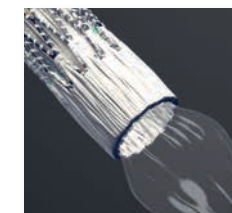
\*SAPIEN 3 Trial, multicentre, prospective, fully CEC adjudicated TAVI trial, as-treated (AT) population, n=96.

Webb J. 1-year outcomes from the SAPIEN 3 Trial. Presented at: EuroPCR 2015; 19 May 2015; Paris, France.

## TRANSFORMATIONAL DESIGN



**ULTRA-LOW DELIVERY PROFILE**  
designed to reduce vascular complications



**STREAMLINED DEPLOYMENT**  
and predictable implantation



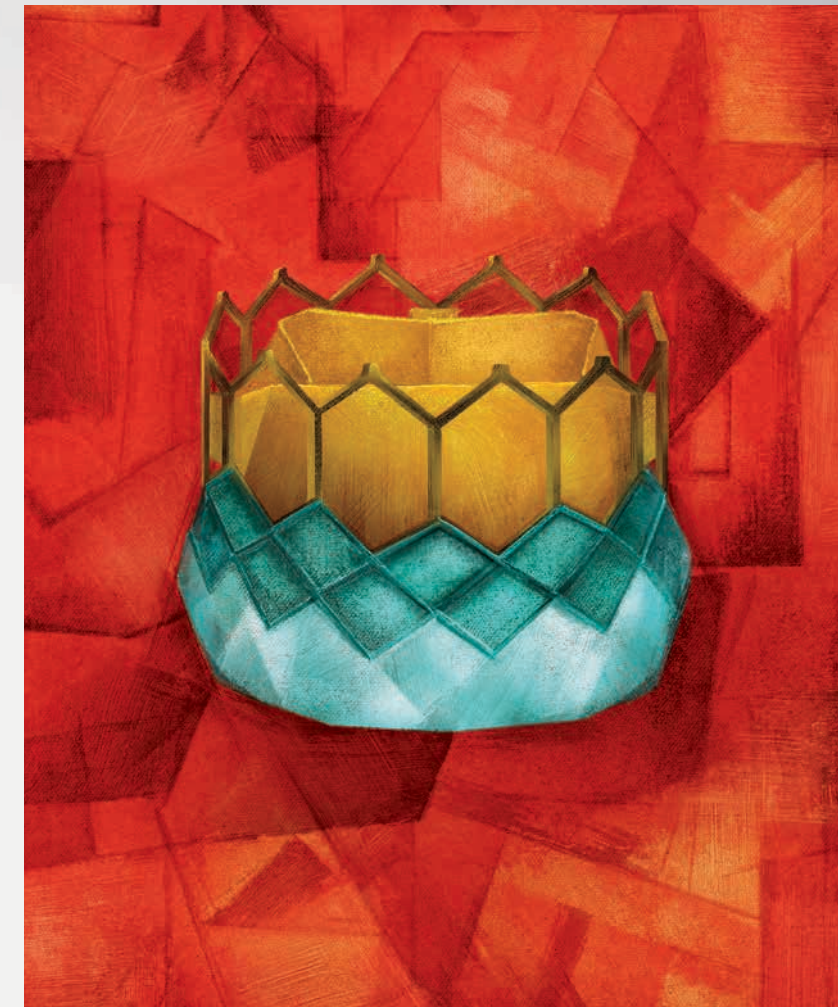
# UNPRECEDENTED OUTCOMES CONTINUED THROUGH 1 YEAR

## TRANSFEMORAL COHORT

### LOW RATE OF PARAVALVULAR LEAK (PAIRED ANALYSIS)\*

30 days **3.2%** **0.0%**

1 year **3.2%** **0.0%**  
Moderate Severe



## TRANSFORMATIONAL DESIGN



**OUTER SEALING SKIRT**  
designed to minimise PV leak



**HIGH RADIAL STRENGTH**  
cobalt chromium alloy frame enables full expansion for apposition at the annulus to reduce PV leak

\*Core lab assessed paravalvular (PV) leak, valve implanted population, n=63. Clinical data on file, Edwards Lifesciences.

# STREAMLINING THE TAVI EXPERIENCE TO PROVIDE BETTER OUTCOMES

## LOW MAJOR VASCULAR COMPLICATION RATES

EVENT RATES: TRANSFEMORAL COHORT, 30-DAY DATA*	
Technical success	95.8%†‡
Major vascular complications	4.2%§
Post-dilatation	4.2%‡
Valve-in-valve	0.0%§
Coronary obstruction	0.0%§

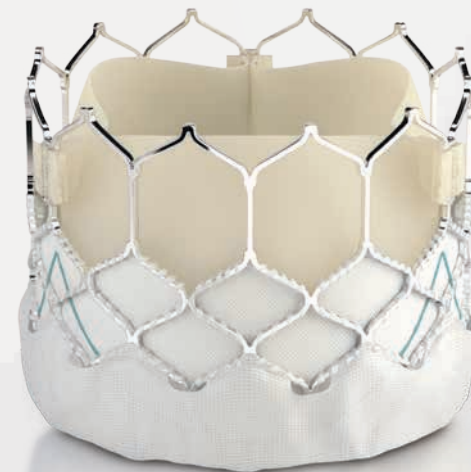
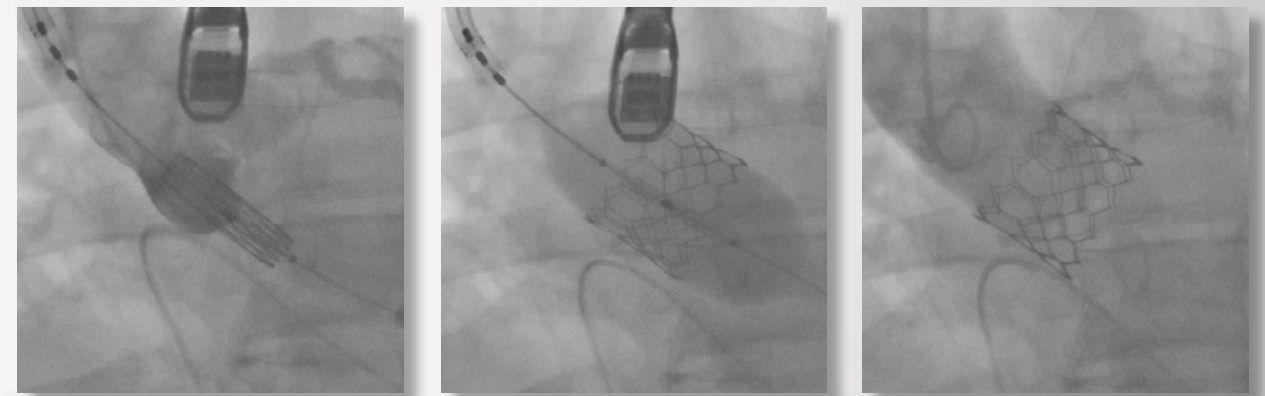
\*SAPIEN 3 Trial, multicentre, prospective, fully CEC adjudicated TAVI trial, AT population, n=96.  
†No procedural mortality, correct positioning, and only one valve implanted.  
‡Clinical data on file, Edwards Lifesciences.  
§Webb J, et al. Multicenter evaluation of a next-generation balloon-expandable transcatheter aortic valve. *J Am Coll Cardiol*. 2014;64:2235-2243.  
||There was no procedural THV-in-THV. Not CE Mark approved for a valve-in-valve indication.

Edwards SAPIEN 3 Transcatheter Heart Valve

Edwards SAPIEN 3 Transcatheter Heart Valve  
EDWARDS COMMANDER DELIVERY SYSTEM

Edwards SAPIEN 3 Transcatheter Heart Valve  
EDWARDS CERTITUDE DELIVERY SYSTEM

## Streamlined Deployment and Predictable Implantation



 **SHORT**  
HOSPITAL LENGTH-OF-STAY\*\*

**0%** RATE OF  
REHOSPITALISATION§



# AT THE FOREFRONT OF EXPANDING TREATMENT POSSIBILITIES



## THE SAPIEN 3 VALVE

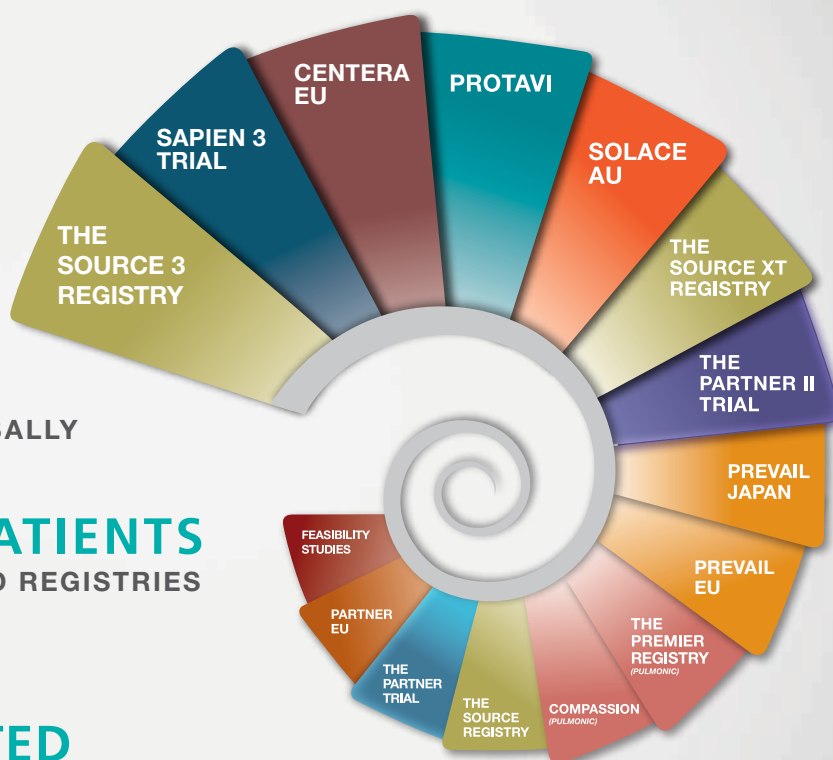
**OVER 1,800 PATIENTS TREATED**

IN US AND EU CLINICAL TRIALS

**THE SAPIEN VALVE PLATFORM**  
THE MOST STUDIED AND IMPLANTED VALVES GLOBALLY

**OVER 30,000 PATIENTS**  
IN CLINICAL STUDIES AND REGISTRIES

**OVER 100,000 PATIENTS TREATED**



## DESIGNING THE FUTURE OF TAVI

For professional use. See instructions for use for full prescribing information, including indications, contraindications, warnings, precautions, and adverse events.

**Caution: CENTERA is a non CE marked device. Not available for commercial use until validly CE marked.**

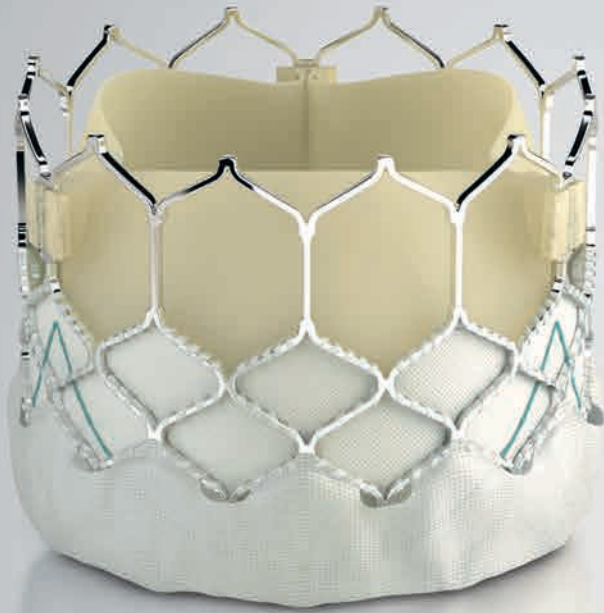
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# Transformational Advances in Valve Design



## INNER AND OUTER SKIRTS

- Polyethylene terephthalate (PET) inner skirt and outer sealing skirt
- Outer sealing skirt is designed to minimise paravalvular (PV) leak

## BOVINE PERICARDIAL TISSUE

- Proven long-term tissue durability\*
- Leaflets optimised for haemodynamics and durability
- Carpentier-Edwards ThermaFix process is intended to reduce the risk of calcification†

## VALVES SIZED TO ACCOMMODATE A WIDE RANGE OF PATIENT ANATOMIES

Edwards SAPIEN 3 Valve Size	Transoesophageal Echocardiogram (TOE)	Native Annulus Area	Area-Derived Diameter
23 mm	18-22 mm	338-430 mm <sup>2</sup>	20.7-23.4 mm
26 mm	21-25 mm	430-546 mm <sup>2</sup>	23.4-26.4 mm
29 mm	24-28 mm	540-683 mm <sup>2</sup>	26.2-29.5 mm

\*Rahimtoola SH. Choice of prosthetic heart valve in adults: an update. *J Am Coll Cardiol.* 2010;55:2413-2426.

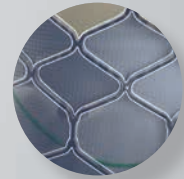
†No clinical data are available with which to evaluate the long-term impact of the Carpentier-Edwards ThermaFix tissue process in patients.

# Valve Design



## FRAME DESIGN

- Enhanced frame geometry and wide strut angles for ultra-low delivery profile
- Wide strut angles provide high fatigue resistance
- Low frame height respects the cardiac anatomy



Edwards SAPIEN 3 Valve Size	Nominal Height
23 mm	18 mm
26 mm	20 mm
29 mm	22.5 mm

## FRAME MATERIAL

- High radial strength cobalt chromium alloy frame enables full expansion for apposition at the annulus to reduce PV leak
- Provides fatigue resistance and high radial strength

## FRAME CONSTRUCTION

- 4 rows and 4 columns between each commissure for high radial strength

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**Edwards SAPIEN 3** Transcatheter Heart Valve

**EDWARDS COMMANDER DELIVERY SYSTEM**

# Ultra-low Delivery Profile With Optimal Positioning Control

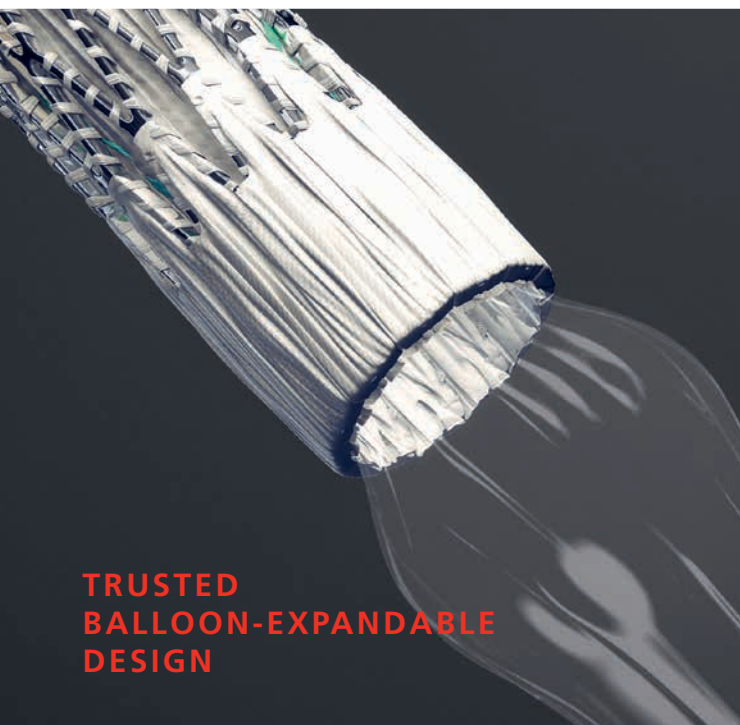
**ULTRA-LOW DELIVERY PROFILE  
(14F eSheath compatible)\***



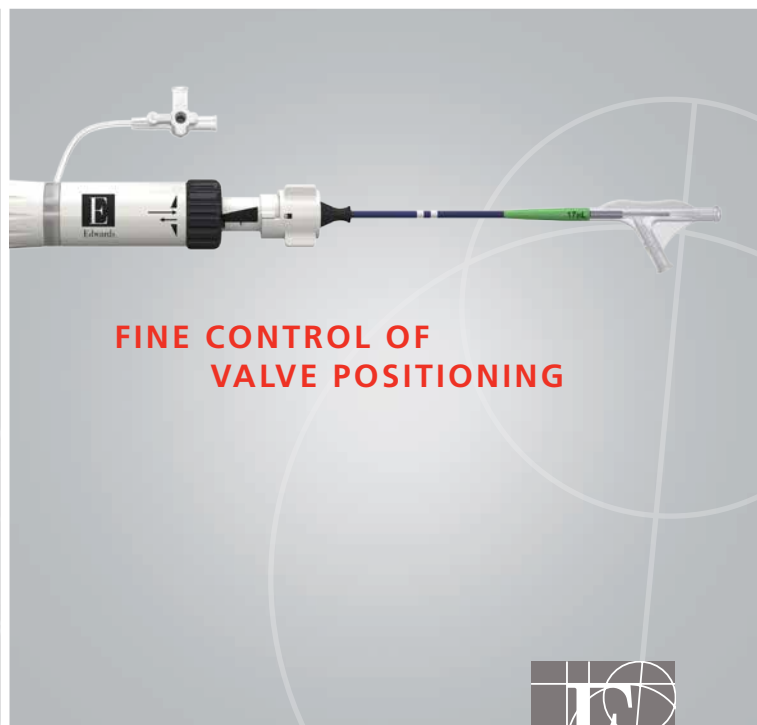
\*14F eSheath is compatible with 23 mm and 26 mm Edwards SAPIEN 3 valves.  
16F eSheath is compatible with 29 mm Edwards SAPIEN 3 valve.



**DUAL ARTICULATION  
FOR COAXIALITY**  
even in challenging anatomies



**TRUSTED  
BALLOON-EXPANDABLE  
DESIGN**



**FINE CONTROL OF  
VALVE POSITIONING**

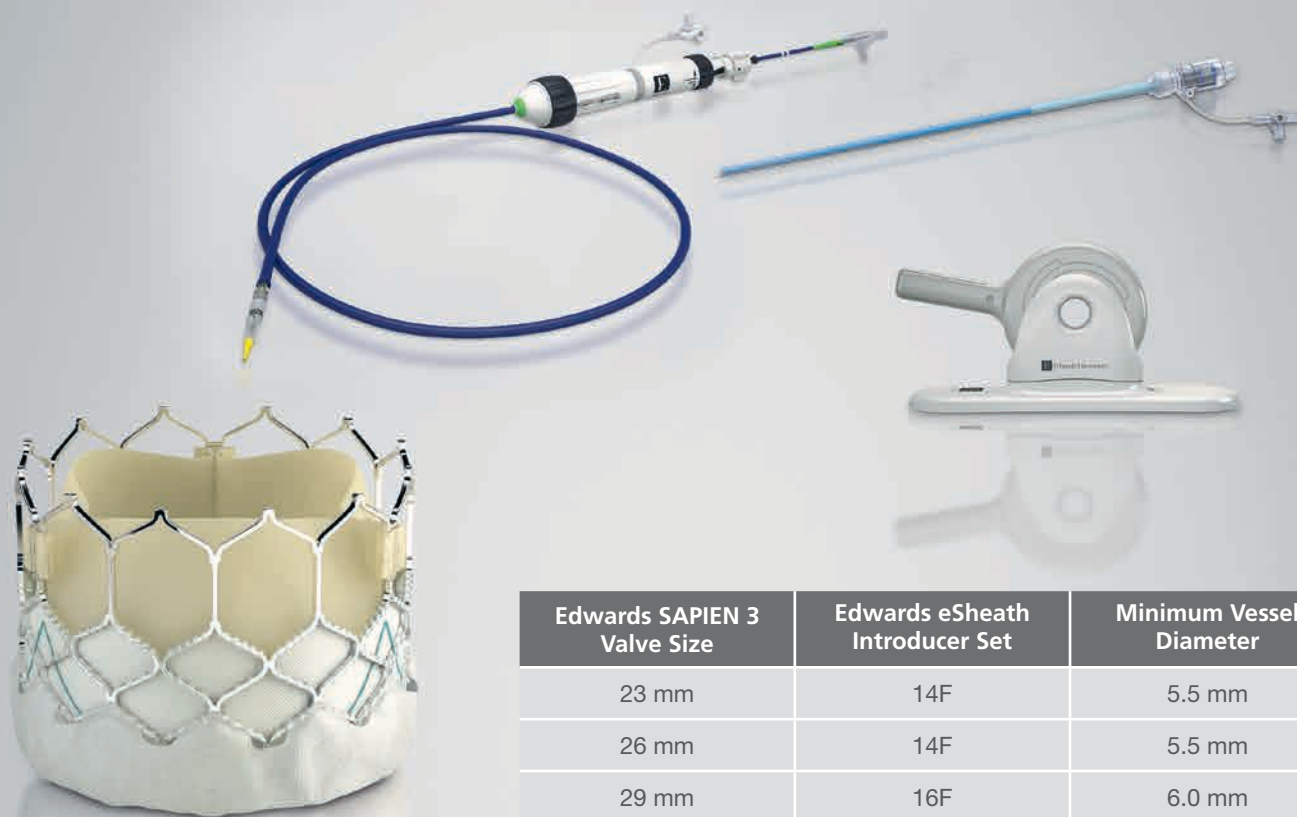


Edwards



# Edwards SAPIEN 3 Transcatheter Heart Valve

## EDWARDS COMMANDER DELIVERY SYSTEM



Edwards SAPIEN 3 Valve Size	Edwards eSheath Introducer Set	Minimum Vessel Diameter
23 mm	14F	5.5 mm
26 mm	14F	5.5 mm
29 mm	16F	6.0 mm

Product Name	23 mm	26 mm	29 mm
Edwards SAPIEN 3 – Edwards Commander Kit	S3TF123	S3TF126	S3TF129
Edwards SAPIEN 3 Transcatheter Heart Valve	9600TFX (23 mm)	9600TFX (26 mm)	9600TFX (29 mm)
Edwards Commander Delivery System*	9610TF23	9610TF26	9610TF29
Edwards eSheath Introducer Set	9610ES14 14F or equivalent		9610ES16 16F or equivalent
Edwards Transfemoral Balloon Catheter	9350BC20	9350BC23	9350BC25
Crimper	9600CR		

\*Includes a Loader, a Qualcrimp Crimping Accessory, and a 2-piece Crimp Stopper.

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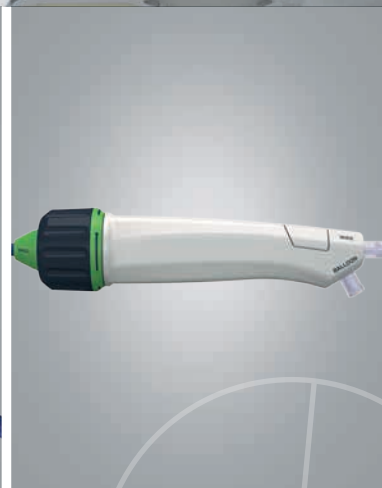
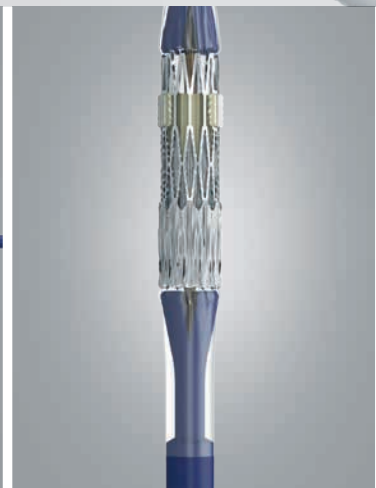
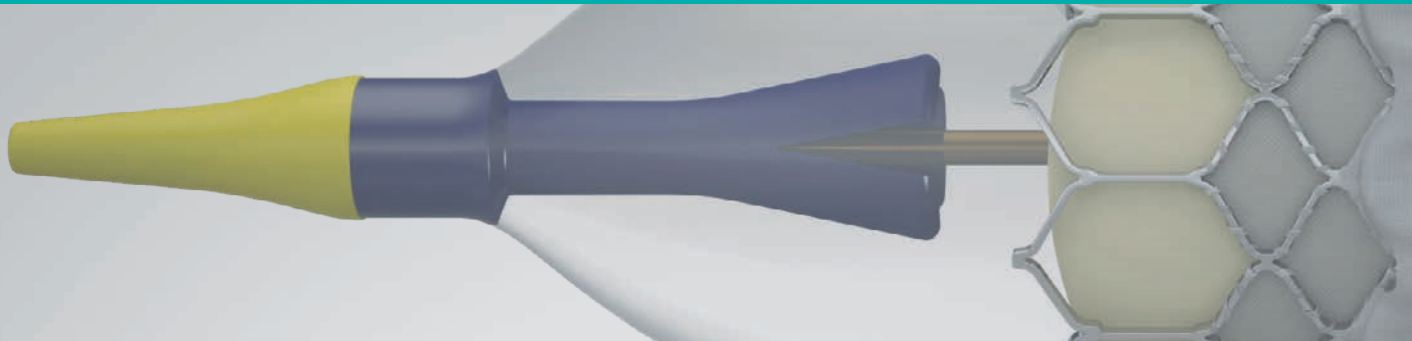


Edwards

**Edwards SAPIEN 3** Transcatheter Heart Valve

**EDWARDS CERTITUDE DELIVERY SYSTEM**

# Seamless Deployment



## **ULTRA-LOW DELIVERY PROFILE**

18F Edwards  
Certitude sheath  
compatible\*

## **INTEGRATED PUSHER**

for streamlined  
procedures

## **ARTICULATION FEATURE**

for ease of  
coaxial positioning

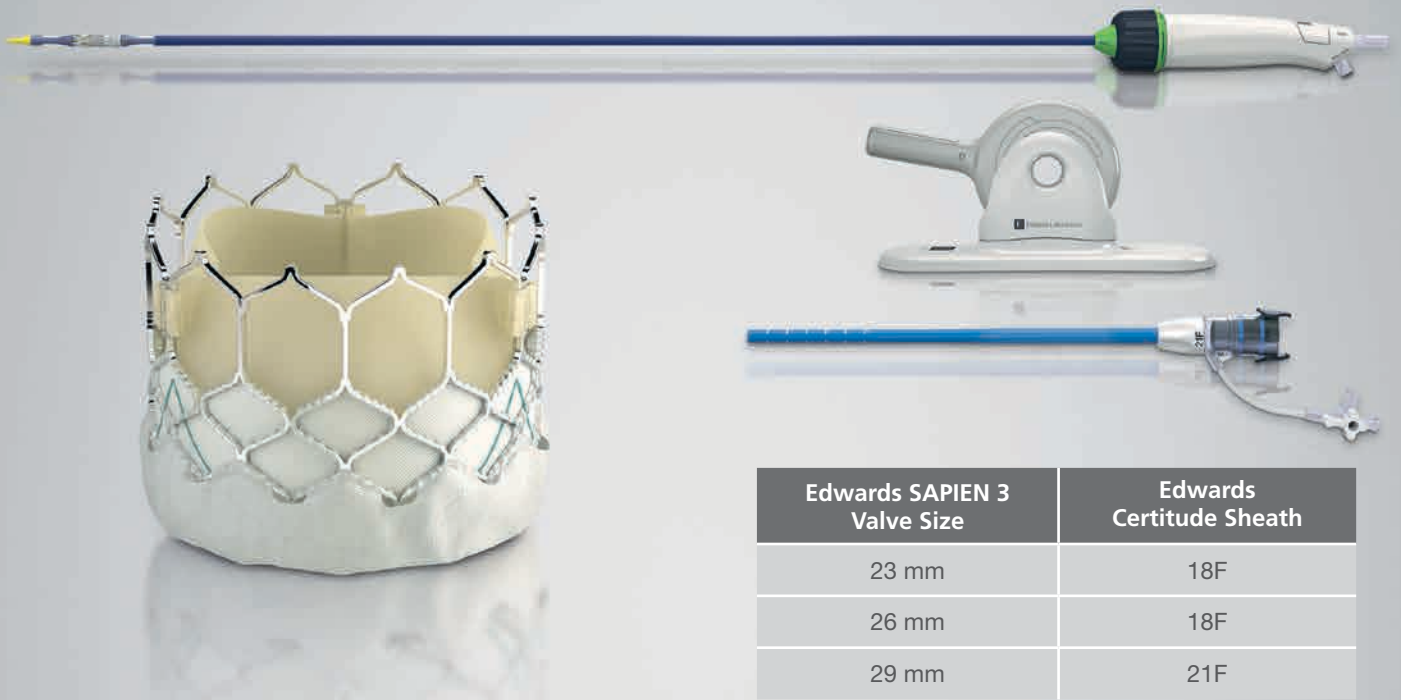
## **ERGONOMICALLY DESIGNED HANDLE**

for improved  
ease of use

\*18F Certitude sheath is compatible with 23 mm and 26 mm Edwards SAPIEN 3 valves.  
21F Certitude sheath is compatible with 29 mm Edwards SAPIEN 3 valve.

# Edwards SAPIEN 3 Transcatheter Heart Valve

## EDWARDS CERTITUDE DELIVERY SYSTEM



Edwards SAPIEN 3 Valve Size	Edwards Certitude Sheath
23 mm	18F
26 mm	18F
29 mm	21F

Product Name	23 mm	26 mm	29 mm
Edwards SAPIEN 3 – Edwards Certitude Kit	S3TA123	S3TA126	S3TA129
Edwards SAPIEN 3 Transcatheter Heart Valve	9600TFX (23 mm)	9600TFX (26 mm)	9600TFX (29 mm)
Edwards Certitude Delivery System	9620TA23	9620TA26	9620TA29
Edwards Certitude Introducer Sheath Set	9620IS18		9620IS21
Crimper	9600CR		
Ascendra Balloon Aortic Valvuloplasty Catheter	9100BAVC		

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