EC CERTIFICATE

Number: 2103732CE01

Full Quality Assurance System

Directive 93/42/EEC on Medical devices, Annex II excluding (4)
(Devices in Class IIa, IIb or III and Devices in Class I in sterile conditions and sterilised systems or procedure packs)

Manufacturer:

Edwards Lifesciences LLC

One Edwards Way
Irvine CA 92614
United States Of America

For the product category(ies)

Systems for Heart Valve Repair and/or Replacement, and Accessories

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EC-Directive which apply to them:

0344

Documents, that form the basis of this certificate:

Certification Notice 2103732CN, initially dated 31 August 2007
Addendum, initially dated 15 October 2007

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Council Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments. The manufacturer has implemented a quality assurance system for design, manufacture and final inspection, that covers the aspects of manufacture concerned with securing and maintaining sterile conditions, for the above mentioned product category in accordance to the provisions of Annex II Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance. Additionally, DEKRA hereby declares that the manufacturer fulfils the relevant provisions as specified in Annex I of Commission Regulation 722/2012 of 8 August, 2012 concerning medical devices manufactured utilising tissue of animal origin. For placing on the market of Class III devices an additional EC design examination certificate according to Annex II (4) is mandatory. The necessary information related to the quality management system of the manufacturer, including facilities and the reference to the relevant documentation, of the products concerned and the assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 7 January 2023
Issued for the first time: 31 August 2007

Revised:23 July 2015
Reissued: 7 January 2018

DEKRA Certification B.V.

drs. G.J. Zoetbrood
Managing Director

ing. A.A.M. Laan
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-certification.com Company registration 09085396

ADDENDUM

Belonging to certificate: 2103732CE01

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Systems for Heart Valve Repair and/or Replacement, and Accessories

Issued to:

Edwards Lifesciences LLC
One Edwards Way
Irvine CA 92614
United States Of America

Location	Activity
Edwards Lifesciences LLC 12050 Lone Peak Parkway Draper, UT 84020 USA	Production and Distribution of Heart Valve Delivery Systems, Valvuloplasty Catheters, Heart Valve Subassemblies (frames) and accessories (introducers, dilators and crimpers)
Edwards Lifesciences (Singapore) Pte Ltd 35 Changi North Crescent Singapore 499641 Singapore	Production of Biological Heart Valves and their subassemblies.
Edwards Lifesciences AG Altsagenstrasse 14 CH-6048 Horw Switzerland	Production and distribution of biological heart valves.
Edwards Lifesciences Services GmbH Edisonstrasse 6 D-85716 Unterschleissheim Germany	European Authorized Representative

DEKRA Certification B.V.

drs. G.J. Zoetbrood
Managing Director

ing. A.A.M. Laan
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

ADDENDUM

Belonging to certificate: 2103732CE01

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Systems for Heart Valve Repair and/or Replacement, and Accessories

Issued to:

Edwards Lifesciences LLC
One Edwards Way
Irvine CA 92614
United States Of America

This certificate covers the following product(s):

Transcatheter Bovine Aortic Heart Valves and Systems for Transfemoral Delivery
- RetroFlex™ Dilator Kit (Class IIa)
- Edwards SAPIEN XT™ Transcatheter Heart Valve (Class III)
- Edwards™ Transfemoral Balloon Catheter (Class III)
- Edwards™ Expandable Introducer Sheath Set (Class III)
- Edwards™ eSheath™ Introducer Set (Class III)
- NovaFlex+ Delivery System (Class III)
- Edwards SAPIEN 3™ Transcatheter Heart Valve (Class III)
- Edwards SAPIEN 3i™ Transcatheter Heart Valve (Class III)
- Edwards Commander™ Delivery System (Class III)

Transcatheter Bovine Pulmonic Heart Valves and Systems for Percutaneous Delivery
- Edwards SAPIEN XT™ Transcatheter Heart Valve (Class III)
- NovaFlex+ Delivery System (Class III)
- Edwards™ Transfemoral Balloon Catheter (Class III)
- RetroFlex™ Dilator Kit (Class IIa)
- Edwards™ Expandable Introducer Sheath Set (Class III)

DEKRA Certification B.V.

drs. G.J. Zoetbrood
Managing Director

ing. A.A.M. Laan
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-certification.com Company registration 09085396

ADDENDUM

Belonging to certificate: 2103732CE01

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Systems for Heart Valve Repair and/or Replacement, and Accessories

Issued to:

Edwards Lifesciences LLC
One Edwards Way
Irvine CA 92614
United States Of America

This certificate covers the following product(s):

Transcatheter Bovine Aortic Heart Valves and Systems for Transapical and Transaortic Delivery
- Edwards SAPIEN XT™ Transcatheter Heart Valve (Class III)
- Ascendra+™ Delivery System (Class III)
- Ascendra+™ Introducer Sheath Set, (Class III)
- Ascendra™ Balloon Aortic Valvuloplasty Catheter (Class III)
- Edwards SAPIEN 3™Transcatheter Heart Valve (Class III)
- Edwards SAPIEN 3i™ Transcatheter Heart Valve (Class III)
- Edwards Certitude™ Delivery System (Class III)
- Edwards Certitude™ Introducer Sheath Set (Class III)

Transcatheter Bovine Aortic Heart Valves and Systems for Transapical, Transaortic and Transfemoral Implantation in Aortic and Mitral Surgical Valves
- Edwards SAPIEN XT™ Transcatheter Heart Valve (Class III)
- NovaFlex+™ Delivery System (Class III)
- Ascendra+™ Delivery System (Class III)
- Edwards™ Expandable Introducer Sheath Set (Class III)
- Ascendra+™ Introducer Sheath Set (Class III)
- RetroFlex™ Dilator Kit (Class IIa)

Accessories for Valve Delivery (Class I, sterile)
- Crimpers
- Crimp Stoppers
- Qualcrimp™ Crimping Accessory

Initial date: 15 October 2007
Revision date: 7 January 2018
DEKRA Certification B.V.

drs. G.J. Zoetbrood
Managing Director

ing. A.A.M. Laan
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-certification.com Company registration 09085396

CERTIFICATE

Number: 3821948

The management system of the organization(s) and locations mentioned on the addendum belonging to:

Edwards Lifesciences LLC

One Edwards Way
Irvine, CA 92614
United States Of America

including the implementation meets the requirements of the standard:

ISO 13485:2016
EN ISO 13485:2016

Scope: Design, development, production and distribution of:

- biological surgical heart valves and accessories (delivery system and inflation device, handles, sizers, trays, suture fasteners, heart support device);
- transcatheter heart valve systems (biological heart valves, delivery systems, balloon catheters) and accessories (access devices, inflation devices and crimpers);
- transcatheter valve repair and replacement systems (implants, delivery system) and accessories (insertion accessories, loading system, dilator kit, stabilizer incl. base and plate);
- annuloplasty rings and accessories (handles, sizers, and trays);
- biologic pericardial patches for the area of heart valve replacement, repair and reconstruction;
- catheters, cannula and occlusion devices and accessories (introducer sheaths, percutaneous insertion kits.

Certificate expiry date: 7 January 2024
Certificate effective date: 8 June 2021
Certified since: 13 December 2018

This certificate is valid for the organization(s) and/or locations mentioned on the addendum.

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

MGMT. SYS. RvA C 589

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-product-safety.com Company registration 09085396

ADDENDUM

To certificate: 3821948

The management system of the organization(s) and/or location(s) of:

Edwards Lifesciences LLC

One Edwards Way
Irvine, CA 92614
United States Of America

Certified organization(s) and/or locations:

Location	Certification scope / Activity
Edwards Lifesciences LLC One Edwards Way Irvine, CA 92614 USA	Design, development, production and distribution of: • biological surgical heart valves and accessories (delivery system and inflation device, handles, sizers, trays, suture fasteners, heart support device); • transcatheter heart valve systems (biological heart valves, delivery systems, balloon catheters) and accessories (access devices, inflation devices and crimpers); • transcatheter valve repair and replacement systems (implants, delivery system) and accessories (insertion accessories, loading system, dilator kit, stabilizer incl. base and plate); • annuloplasty rings and accessories (handles, sizers, and trays); • biologic pericardial patches for the area of heart valve replacement, repair and reconstruction; • catheters, cannula and occlusion devices and accessories (introducer sheaths, percutaneous insertion kits.
Edwards Lifesciences LLC 12050 Lone Peak Parkway Draper, UT 84020 USA	Production and distribution of: • biological surgical heart valve accessories (delivery system and inflation device, handles, sizers, trays, suture fasteners, heart support device); • transcatheter heart valve systems (biological heart valve delivery systems, balloon catheters) and accessories (access devices, inflation devices and crimpers); • transcatheter valve repair and replacement systems (implants, delivery system) and accessories (insertion accessories, loading system, dilator kit, stabilizer incl. base and plate); • annuloplasty rings and accessories (handles, sizers, and trays); • catheters, cannula and occlusion devices and accessories (introducer sheaths, percutaneous insertion kits.

ADDENDUM

To certificate: 3821948

The management system of the organization(s) and/or location(s) of:

Edwards Lifesciences LLC

One Edwards Way
Irvine, CA 92614
United States Of America

Certified organization(s) and/or locations: continued

Location	Certification scope / Activity
Edwards Lifesciences (Singapore) Pte Ltd 35 Changi North Crescent Singapore 499641 Singapore	Production and distribution of: • biological surgical heart valves; • transcatheter heart valve systems; • transcatheter valve repair and replacement systems (implants).
Edwards Lifesciences Costa Rica S.R.L. La Lima Zona Franca, Edificio Multitenant Modulos 1-3, La Lima, Cartago, Costa Rica	Production and distribution of: • biological heart valve replacement subassemblies.
Edwards Lifesciences Costa Rica S.R.L. Zona Franca La Lima de la entrada de Pequeño Mundo 100 mts oeste y 200 mts sur, Finca 31 y 32, Guadalupe Cartago, Costa Rica	Production and distribution of: • transcatheter heart valves.
Edwards Lifesciences LTD 10 Earhart Ave Shannon Industrial Estates Shannon, County Clare V14 P638 Ireland	Production and distribution of: • transcatheter valve repair and replacement systems (implants, delivery system) and accessories (insertion accessories, loading system, dilator kit, stabilizer incl. base and plate).

Addendum expiry date: 7 January 2024
Addendum effective date: 8 June 2021

EC Declaration of Conformity

Edwards

Manufacturer:	Edwards Lifesciences LLC One Edwards Way, Irvine, CA 92614, USA
European Representative:	Edwards Lifesciences Services GmbH Edisonstraße 6, 85716 Unterschleißheim, Germany
Product Category:	Systems for Heart Valve Repair and/or Replacement, and Accessories
Products:	Transfemoral, Transapical, Transaortic and Pulmonic THV Systems Model codes, Names, Types: see product list
Classification / Rule(s):	See product list (according to Annex IX of the Medical Device Directive)
Conformity Assessment Route:	Annex II
UMDNS / GMDN Nomenclature:	See product list
Applicable Standards:	The harmonized standards and other consensus standards used (specified by numbers, titles, editions and/or dates of issue) in relation to which conformity is declared, as well as the identification of internal data confirming compliance, are provided in the Essential Requirements Checklists for the products identified in this declaration.
Start of CE Marking:	See product list

We herewith declare that the distributed CE marked products specified above conform to the product(s) covered by the "CE Marking of Conformity Certificate, Medical Devices" issued and delivered by DEKRA Certification B.V., Arnhem, the Netherlands, in accordance with Annex II of the "EC-Directive", Council Directive 93/42/EEC of 14 June 1993 concerning medical devices and with the particular requirements laid down in Annex I of Commission Regulation 722/2012 of 8 August 2012 concerning medical devices manufactured utilizing tissue of animal origin. All supporting documentation is retained at the premises of the manufacturer.

In addition, we ensure and declare that the distributed CE marked products meet the provisions of the EC-Directives that apply to them. This declaration is based on the application of the Quality System approved for the design, manufacture and final inspection of the products concerned, in accordance with Annex II of the EC-Directive. The conformity of the full quality assurance system is described in the CE Marking of Conformity Certificate issued by DEKRA Certification B.V.

EC Declaration of Conformity

Edwards

The manufacturer has established and is maintaining a quality management system that meets the requirements of ISO 13485, as supported by the following certificates:

Certificate No.	Valid until	Holder of Certificate	Certified Locations/Facilities*
Quality Management System Certificates			
3805473	2019-03-01	Edwards Lifesciences Pte Ltd, Singapore	Edwards Lifesciences Pte Ltd 35 Changi North Crescent Singapore 499641, Singapore
Quality Management System Certificates			
3805474**	2018-12-31	Edwards Lifesciences LLC, Irvine	Edwards Lifesciences LLC One Edwards Way Irvine, CA 92614 USA
			Edwards Lifesciences AG Altsagenstrasse 14 6048 Horw, Switzerland
			Edwards Lifesciences Pte Ltd 35 Changi North Crescent Singapore 499641, Singapore
			Edwards Lifesciences LLC 12050 Lone Peak Parkway Draper, UT 84020 USA
			Edwards Lifesciences Costa Rica S.R.L. La Lima Zona Franca Edificio Multitenant Modulos 1-3. La Lima, Cartago, Costa Rica
			Edwards Lifesciences LLC 1212 Alton Parkway Irvine, CA 92606 USA
			Edwards Lifesciences LLC 1821 Kettering Irvine, CA 92614 USA
CE Marking of Conformity Certificate			
2103732CE01	2023-01-07	Edwards Lifesciences LLC, Irvine	Edwards Lifesciences LLC One Edwards Way Irvine, CA 92614 USA
			Edwards Lifesciences AG Altsagenstrasse 14, 6048 Horw, Switzerland
			Edwards Lifesciences Pte Ltd 35 Changi North Crescent Singapore 499641
			Edwards Lifesciences Ltd 12050 Lone Peak Parkway Draper, UT 84020 USA
			Edwards Lifesciences Services GmbH Edisonstrasse 6 85716 Unterschleissheim, Germany
EC Design-Examination Certificates			
2103732DE01 2103732DE06 2103732DE09 2103732DE10	2023-01-07	Edwards Lifesciences LLC, Irvine	Edwards Lifesciences LLC One Edwards Way Irvine, CA 92614 USA
			Edwards Lifesciences AG Altsagenstrasse 14 Horw, Switzerland

EC Declaration of Conformity

Edwards

Certificate No.	Valid until	Holder of Certificate	Certified Locations/Facilities*
			Edwards Lifesciences Pte Ltd 35 Changi North Crescent Singapore 499641
			Edwards Lifesciences LLC 12050 Lone Peak Parkway Draper, UT 84020 USA

* Refer to certificates for scope of activities performed at these facilities; ** Certification to ISO 13485:2003

Notified Body: DEKRA Certification B.V.
(Identification No. 0344) Arnhem, The Netherlands

This declaration of conformity is issued under the sole responsibility of Edwards Lifesciences LLC.

Signed for and on behalf of manufacturer: Edwards Lifesciences LLC

Location: Irvine, USA
Date: 04 January 2018

Rand Pugmire
Manager RA Program Management, THV Regulatory Affairs
Edwards Lifesciences LLC

EC Declaration of Conformity

Edwards

Product List:

Trade Name – Classification / Rule(s) [Applicable Certificates]	Model(s)	UMDNS Code	GMDN Code	Start of CE Marking (see NOTES at end of table)
Transcatheter Bovine Heart Valves [implant/THV] – Class III / Rules 8, 17				
Edwards SAPIEN XT™ Transcatheter Heart Valve [2103732(CE01, DE06)]	9300TFX	15870	60247 (Pulmonic)	18 January 2016[11]
Edwards SAPIEN XT™ Transcatheter Heart Valve [2103732(CE01, DE01, DE09, DE10)]	9300TFX	15870	60245 (Aortic, and Aortic Valve in Surgical Valve) 60246 (Mitral Valve in Surgical Valve)	11 March 2010[2a] 22 July 2010[3] 25 February 2011[4] 27 April 2012[2b] 30 May 2012[5] 30 January 2014[7, 8, 9] 9 September 2014[10]
Edwards SAPIEN 3™ Transcatheter Heart Valve [2103732(CE01, DE01, DE09)]	9600TFX	15870	60245 (Aortic)	27 January 2014[6] 28 March 2014[5] 16 August 2016 [10,12]
Accessories for Valve Delivery – Class I (sterile) / Rule 1				
Crimper [2103732(CE01)]	9350CR	16463	16463	25 February 2011[4] 27 May 2011[2] 30 January 2014[7, 8, 9]
	9600CR			27 January 2014
Qualcrimp™ Crimping Accessory [2103732(CE01)]	See NOTE[1]	15571	Not applicable	11 March 2010[2a] 30 January 2014[9]
Predilation Catheters, Percutaneous – Class III / Rule 6				
Edwards™ Transfemoral Balloon Catheter [2103732(CE01, DE01)]	9350BC16	17453	17453	9 September 2014[10]
Edwards™ Transfemoral Balloon Catheter [2103732(CE01, DE01, DE06)]	9350BC20 9350BC23			1 February 2011[2a] 18 January 2016[11]
Edwards™ Transfemoral Balloon Catheter [2103732(CE01, DE01, DE06)]	9350BC25			27 April 2012[2b] 18 January 2016[11]
Systems for Percutaneous Delivery – Class IIa / Rule 6				
RetroFlex® Dilator Kit [2103732(CE01)]	9100DKS	10678	58865	27 September 2007[2a] 30 January 2014[9]
Systems for Percutaneous Delivery – Class III, Rule 6				
NovaFlex+™ Delivery System [2103732(CE01, DE01, DE06, DE10)]	9355FS20	17846	60245 (Aortic)	9 September 2014[10]
	9355FS23 9355FS26 9355FS29		60245 (Aortic) 60247 (Pulmonic)	27 May 2011[2a] 30 January 2014[9]
				27 April 2012[2b]
				18 January 2016[11]
Edwards™ Expandable Introducer Sheath Set [2103732(CE01, DE01, DE06, DE10)]	916ES23 918ES26	10678	58865	22 February 2011 30 January 2014[9] 28 November 2017
	920ES29			26 September 2011 28 November 2017
Edwards™ eSheath Introducer Set [2103732(CE01, DE01, DE06, DE10)]	9610ES14			09 January 2012 28 November 2017
	9610ES16			15 November 2013 28 November 2017
Systems for Percutaneous Delivery – Class III, Rule 7				
Edwards Commander™ Delivery System [2103732(CE01, DE01)]	9610TF20 9610TF23 9610TF26 9610TF29	17846	60245 (Aortic)	16 August 2016
				27 January 2014

EC Declaration of Conformity

Edwards

Product List:

Trade Name – Classification / Rule(s) [Applicable Certificates]	Model(s)	UMDNS Code	GMDN Code	Start of CE Marking (see NOTES at end of table)
Systems for Transapical Delivery – Class III / Rule 6				
Edwards Certitude™ Delivery System [2103732(CE01, DE09)]	9620TA20 9620TA23 9620TA26 9620TA29	17453	60245 (Aortic)	16 August 2016[12] 27January 2014
Edwards Certitude™ Introducer Sheath Set [2103732(CE01, DE09)]	9620IS18 9620IS21	10678	58865	16 August 2016 [12] 27January 2014
Predilation Catheters, Transapical and Transaortic – Class III / Rule 6				
Ascendra® Balloon Aortic Valvuloplasty Catheter [2103732(CE01, DE09)]	9100BAVC	17453	17453	25 February 2011[4] 30 May 2012[5]
Systems for Transapical and Transaortic Delivery – Class III / Rule 6				
Ascendra+™ Delivery System [2103732(CE01, DE09, DE10)]	9355AS23 9355AS26	17453	60245 (Aortic) 60246 (Mitral Valve in Surgical Valve)	30 May 2012[5] 30 January 2014[7, 8]
	9355AS29			30 May 2012[5]
Edwards Certitude™ Delivery System [2103732(CE01, DE09)]	9620TA20 9620TA23 9620TA26 9620TA29	17453	60245 (Aortic)	16 August 2016[12] 28 March 2014[5]
Ascendra+™ Introducer Sheath Set [2103732(CE01, DE09, DE10)]	9350IS23 9350IS26	10678	58865	30 May 2012[5] 30 January 2014[7, 8]
	9350IS29			30 May 2012[5]
Edwards Certitude™ Introducer Sheath Set [2103732(CE01, DE09)]	9620IS18 9620IS21			28 March 2014[5]

NOTES:

[1] Packaged with the NovaFlex+ delivery systems, Commander delivery systems, and Certitude delivery systems.
[2a] Aortic, transfemoral – 23mm and 26mm systems
[2b] Aortic, transfemoral – 29mm systems
[3] Aortic, transapical – 23mm and 26mm systems
[4] Aortic, transapical – 29mm systems
[5] Aortic, transapical / transaortic – 23mm, 26mm, and 29mm systems
[6] Aortic, transfemoral/ transapical – 23mm, 26mm, and 29mm systems
[7] Aortic, THV-in-Surgical Valve, transaortic – 23mm and 26mm systems
[8] Aortic/Mitral, THV-in-Surgical Valve, transapical – 23mm and 26mm systems
[9] Aortic, THV-in-Surgical Valve, transfemoral – 23mm and 26mm systems
[10] Aortic, transfemoral – 20mm system
[11] Pulmonic, transfemoral – 23mm, 26mm, and 29mm systems
[12] Aortic, transapical/transaortic – 20mm system

Edwards SAPIEN 3 Transcatheter Heart Valve

DESIGNING THE FUTURE OF TAVI

TRANSFORMATIONAL DESIGN THAT DELIVERS UNPRECEDENTED OUTCOMES

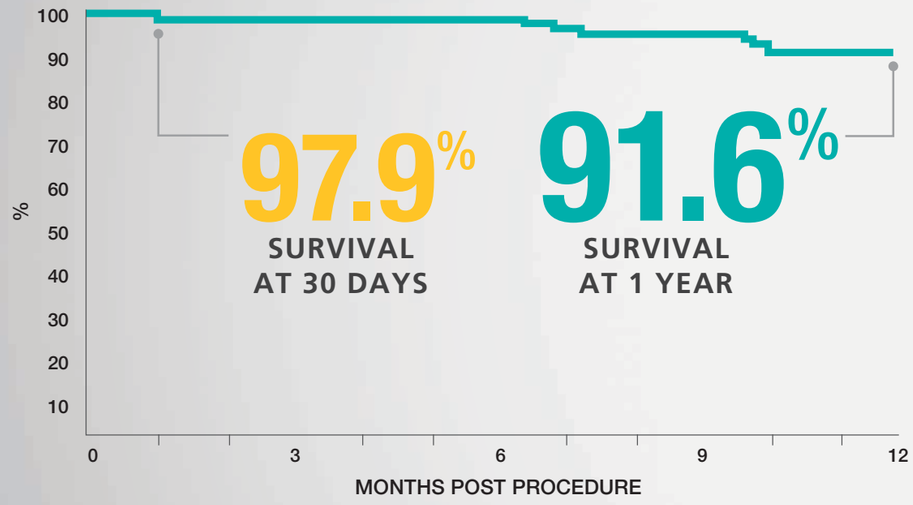
Edwards

Edwards SAPIEN 3 Transcatheter Heart Valve

UNPRECEDENTED OUTCOMES CONTINUED THROUGH 1 YEAR

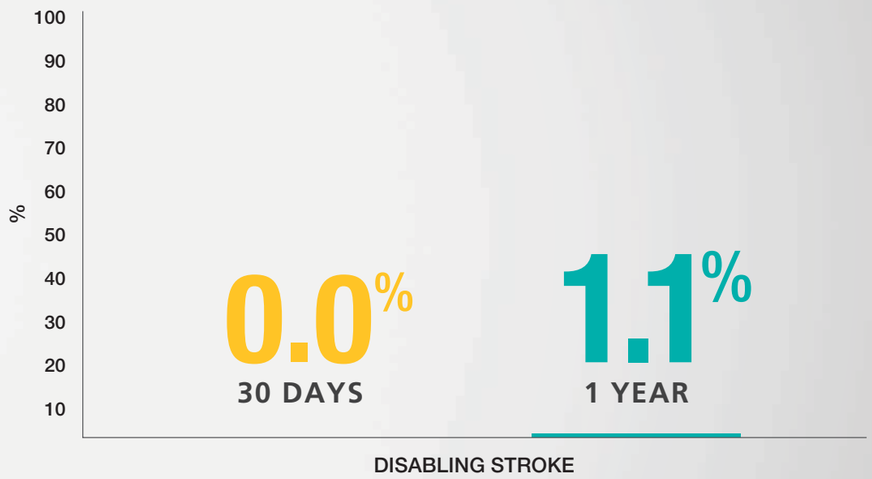
THE HIGHEST SURVIVAL EVER REPORTED IN A CLINICAL TRIAL AT 1 YEAR*

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.

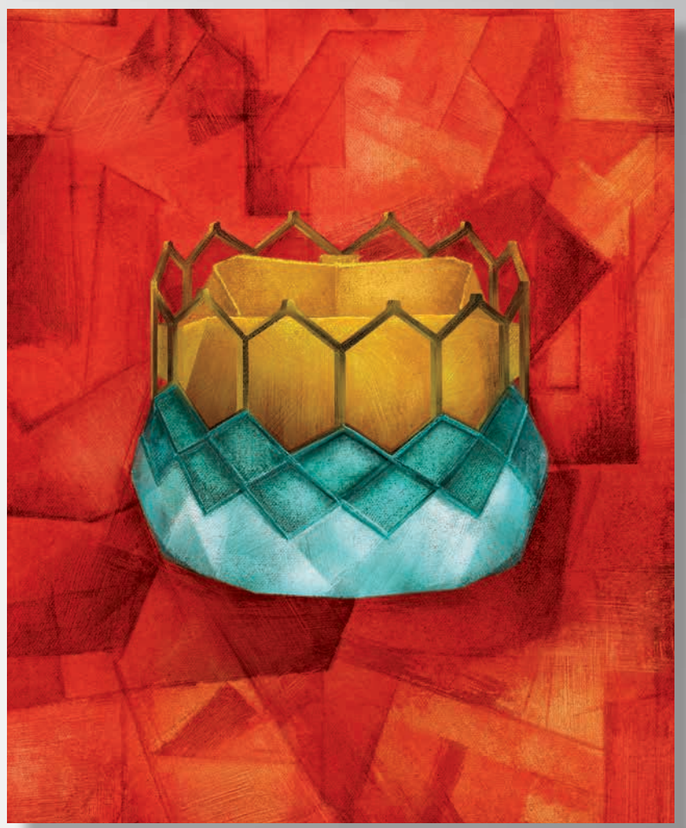
Webb J. 1-year outcomes from the SAPIEN 3 Trial. Presented at: EuroPCR 2015; 19 May 2015; Paris, France.

TRANSFORMATIONAL DESIGN

ULTRA-LOW DELIVERY PROFILE
designed to reduce vascular complications

STREAMLINED DEPLOYMENT
and predictable implantation

UNPRECEDENTED OUTCOMES CONTINUED THROUGH 1 YEAR

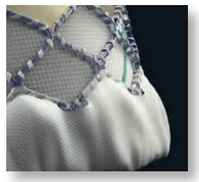


TRANSFEMORAL COHORT

LOW RATE OF PARAVALVULAR LEAK (PAIRED ANALYSIS)*

	Moderate	Severe
30 days	3.2%	0.0%
1 year	3.2%	0.0%

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.

Edwards SAPIEN 3 Transcatheter Heart Valve

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%§

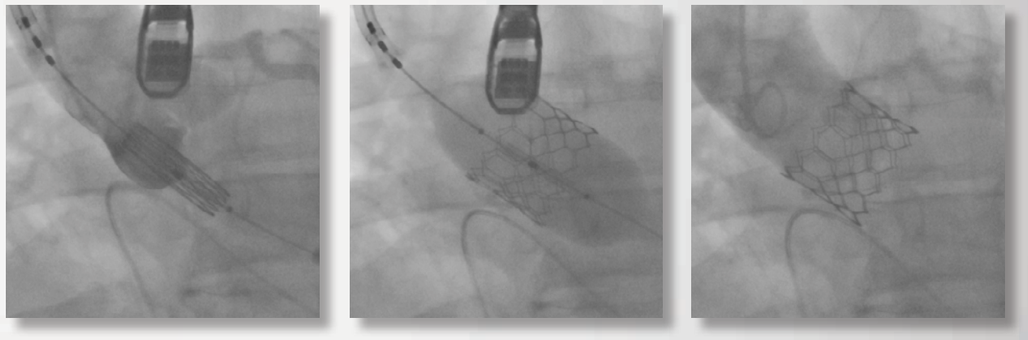
*SAPIEN 3 Trial, multicentre, prospective, fully CEC adjudicated TAVI trial, AT population, n=96.
†No procedural mortality, correct positioning, and only one valve implanted.
‡Clinical data on file, Edwards Lifesciences.
§Webb J, et al. Multicenter evaluation of a next-generation balloon-expandable transcatheter 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*‡

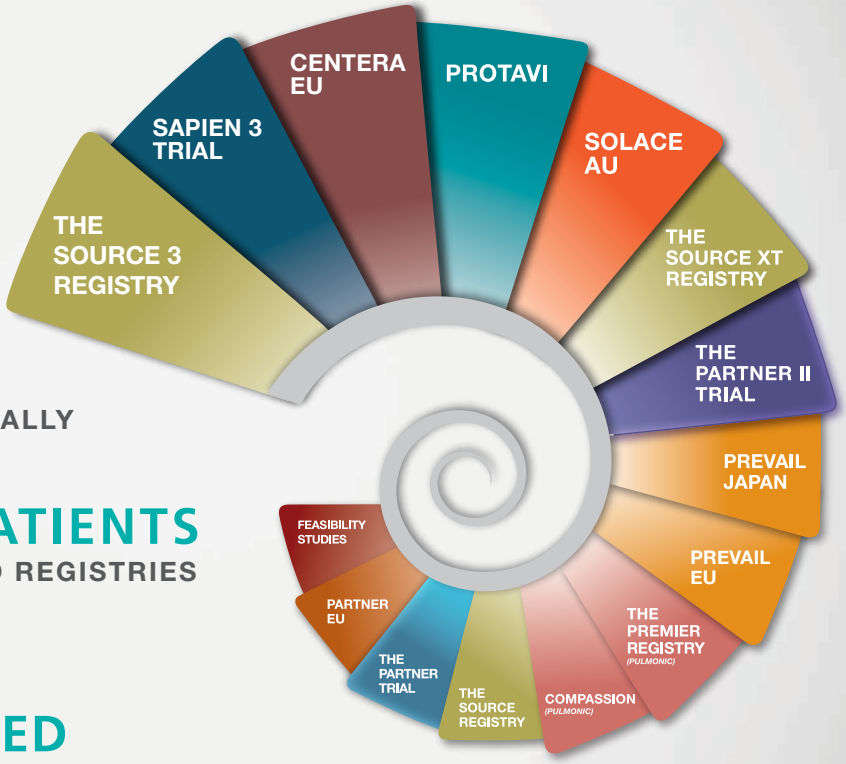
0% RATE OF
REHOSPITALISATION§

Edwards SAPIEN 3 Transcatheter Heart Valve

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

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

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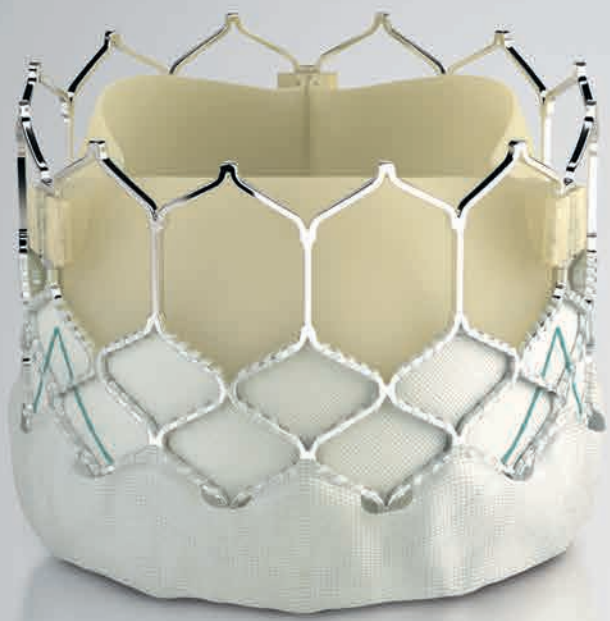
Transformational Advances in Valve Design



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^2	20.7-23.4 mm
26 mm	21-25 mm	430-546 mm^2	23.4-26.4 mm
29 mm	24-28 mm	540-683 mm^2	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.

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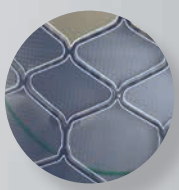
Valve Design

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

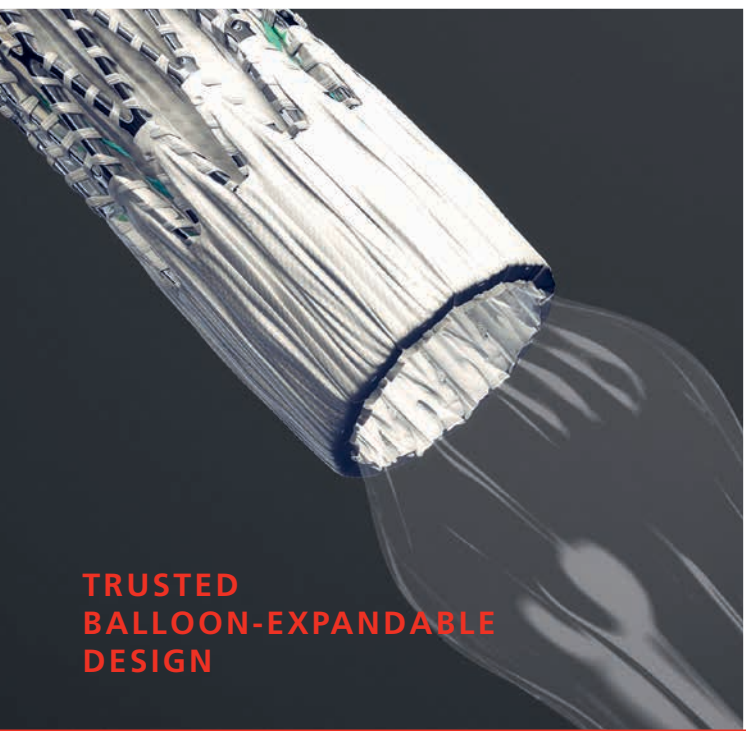
Ultra-low Delivery Profile With Optimal Positioning Control

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



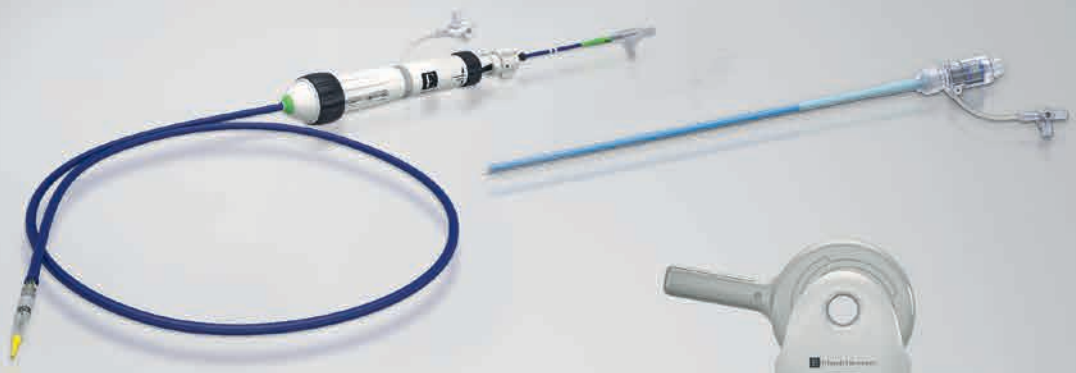
TRUSTED BALLOON-EXPANDABLE DESIGN

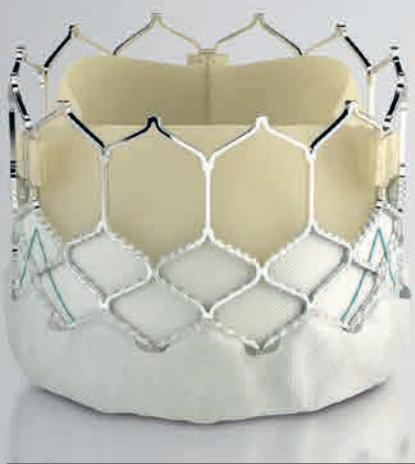
FINE CONTROL OF VALVE POSITIONING

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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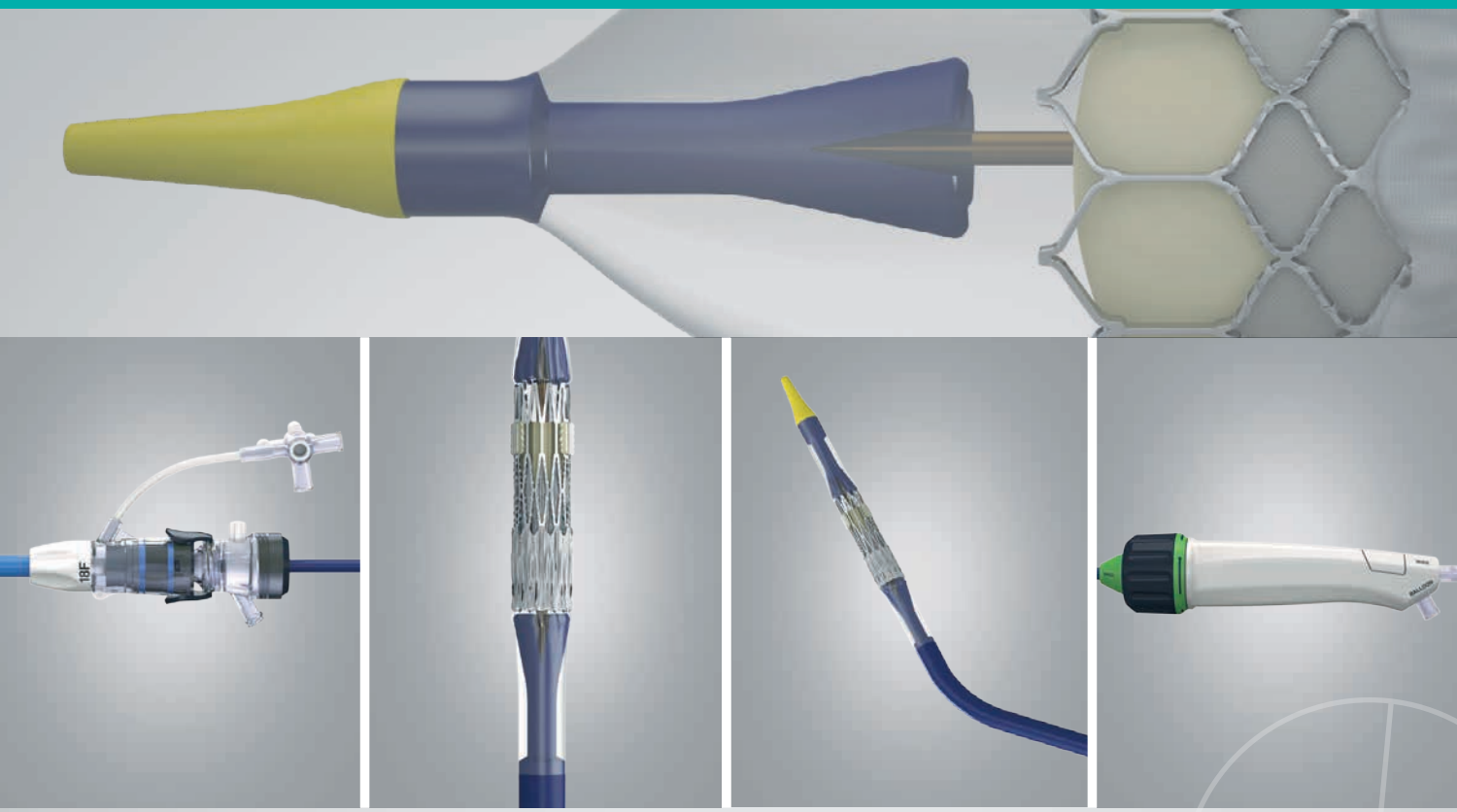
Edwards SAPIEN 3 Transcatheter Heart Valve

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

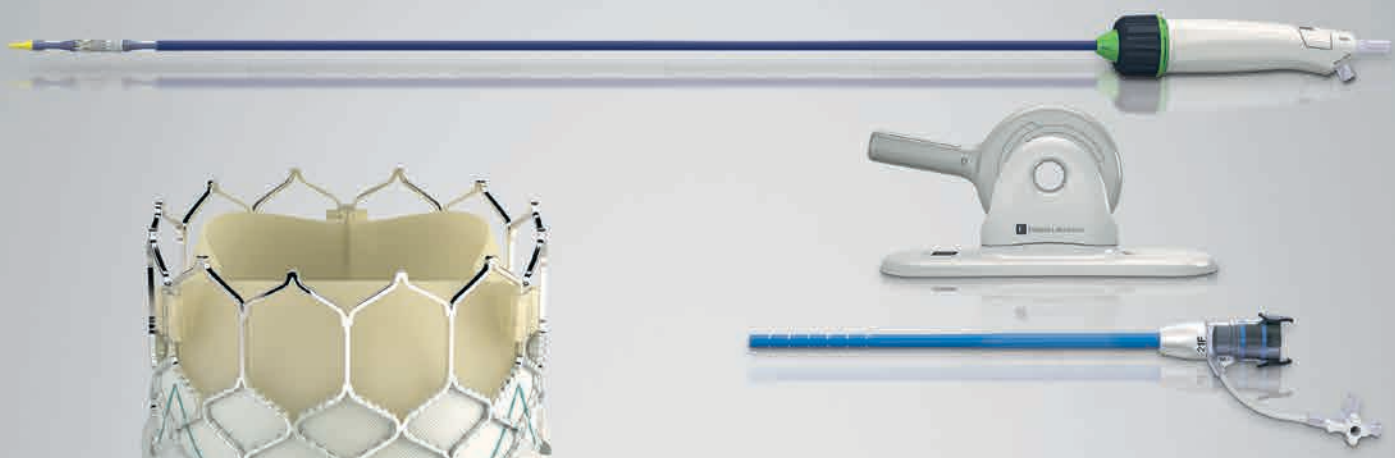
ERGONOMICALLY DESIGNED HANDLE
for improved ease of use

*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

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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