



Edwards SAPIEN Transcatheter Heart Valve

RetroFlex Transfemoral Valve Delivery System

A Breakthrough Solution To An Age-Old Problem.

Transcatheter Technology For Severe Aortic Stenosis

From the leader in the science of heart valve technology comes an exciting breakthrough in transfemoral aortic heart valve replacement: a balloon-expandable valve, mounted on a stainless steel stent frame. The Edwards SAPIEN transcatheter heart valve is designed to provide excellent hemodynamics, uniform leaflet coaptation and a large, consistent effective orifice area. Now, aortic valve replacement is possible without the invasive effects of open heart surgery and cardiopulmonary bypass.



Innovative Heart Valve Design

The Edwards SAPIEN transcatheter heart valve is built upon Edwards Lifesciences' more than forty years of continuous refinement in heart valve technology. Constructed from bovine pericardial tissue treated with the Carpentier-Edwards ThermaFix* process, the Edwards SAPIEN transcatheter heart valve incorporates proprietary, PeriMap leaflet deflection technology. This leading edge process helps ensure that leaflets are precisely matched for thickness, uniformity and elasticity, providing excellent coaptation.



The articulating valve delivery system is designed to safely traverse the arch and cross the valve.

Articulating Delivery System

The RetroFlex transfemoral valve delivery system is designed to deliver utmost control during valve placement. The articulating distal end facilitates guidance over the arch and through the center of the aortic valve. The braided catheter shaft enhances pushability for ease of delivery, and the patented sheath achieves excellent hemostasis with tri-seal valve technology.



Handpiece is ergonomically designed for maximum control.



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Complete System 23 mm		
Re-Order Number	Description	Size
9100RF123	Complete System: valve and transfemoral valve delivery system and accessory components	23 mm
Includes:		
	9000TFX Edwards SAPIEN transcatheter heart valve	23 mm
	9100DKS RetroFlex 4-piece dilator kit	16F, 18F, 20F, 22F
	9100SL23 RetroFlex introducer sheath set	22F
	9100FC RetroFlex delivery catheter	n/a
	9100BC20 RetroFlex balloon catheter, pre-dilatation	20 mm
	9100BC23 RetroFlex balloon catheter, delivery	23 mm
	9100CR23 Crimper	23 mm
	96362 Atrion QL 2350 inflation device (2)	25 ml

Complete System 26 mm		
Re-Order Number	Description	Size
9100RF126	Complete System: valve and transfemoral valve delivery system and accessory components	26 mm
Includes:		
	9000TFX Edwards SAPIEN transcatheter heart valve	26 mm
	9100DKS RetroFlex 4-piece dilator kit	16F, 18F, 20F, 22F
	9100SL26 RetroFlex introducer sheath set	24F
	9100FC RetroFlex delivery catheter	n/a
	9100BC23 RetroFlex balloon catheter, pre-dilatation	23 mm
	9100BC26 RetroFlex balloon catheter, delivery	26 mm
	9100CR26 Crimper	26 mm
	96362 Atrion QL 2350 inflation device (2)	25 ml

*No clinical data are available which evaluate the long-term impact of the Edwards Lifesciences tissue treatment in patients.

Not available for sale in the United States.

Edwards Lifesciences devices placed on the European market meeting the essential requirements referred to in Article 3 of the Medical Device Directive 93/42/EEC bear the CE marking of conformity.

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