



# Break Through The Challenges Of High-Risk AS Therapy.

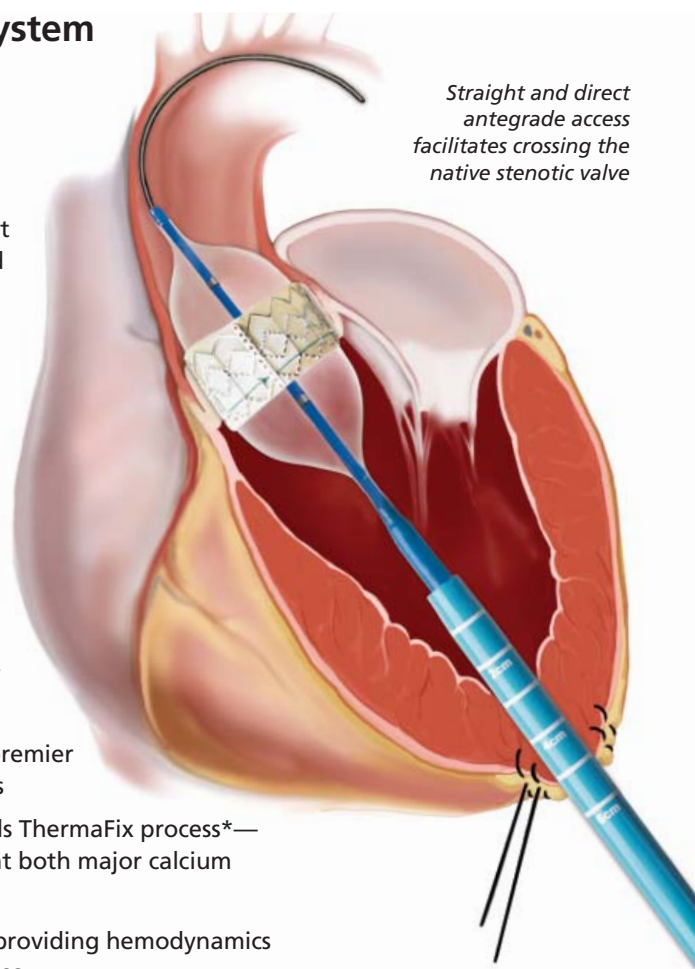
## Edwards SAPIEN Transcatheter Heart Valve Ascendra Transapical Valve Delivery System

### Direct Transapical Approach To Aortic Valve Replacement

- Designed with the surgeon in mind, to help treat a patient population who previously may not have been considered for traditional open-chest aortic valve replacement
- Minimally invasive procedure may be performed with or without cardiopulmonary bypass
- For patients with tortuous peripheral/iliac vasculature, atherosclerotic and porcelain aorta, severe peripheral vascular disease or small vasculature

### Exceptional Performance In A Sutureless Heart Valve

- The Edwards SAPIEN transcatheter heart valve is bench tested to ISO and FDA standards for the proven durability you expect from the leader in heart valve technology
- Incorporates the same manufacturing processes used on premier Carpentier-Edwards PERIMOUNT Magna pericardial valves
- The tissue leaflets are treated with the Carpentier-Edwards ThermoFix process\*—the only dual-action tissue treatment designed to confront both major calcium binding sites: residual glutaraldehydes and phospholipids
- Low-profile, sutureless valve reduces implant time, while providing hemodynamics comparable to traditional, surgically-implanted heart valves



*Straight and direct  
antegrade access  
facilitates crossing the  
native stenotic valve*



*Rigid, concentric frame  
maintains shape for  
consistent effective orifice  
area within native  
calcific valve*







### Delivering Confidence And Control

- The Ascendra delivery system puts controlled insertion and precise valve placement in your hands
- Straight sheaths and catheters are easy to pass over the wire, directly to the valve, allowing surgeons to complete the procedure in less time than a conventional AVR in most cases
- Volume based balloon deployment reduces the risk of under or over sizing



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## Ascendra Transapical Valve Delivery System

Re-Order Number/Size		Model Description
<b>9100AS123</b> 23mm	<b>9100AS126</b> 26mm	<b>Complete system: valve and transapical valve delivery system and accessory components listed below</b>
9000TFX 23mm	9000TFX 26mm	<b>Edwards SAPIEN transcatheter heart valve</b> Stainless steel structure ensures firm fixation with minimal recoil, PET fabric cuff, bovine pericardial tissue with ThermoFix tissue process 
9100IS 26 F	9100IS 26 F	<b>Ascendra introducer sheath set</b> A single introducer sheath, designed for all anatomies, is kink-resistant for smooth catheter passage and at the same time, flexible to avoid trauma to the heart 
9100BAVC 20mm	9100BAVC 20mm	<b>Ascendra balloon aortic valvuloplasty catheter</b> Shortened balloon aortic valvuloplasty catheter is tailored for apical access and aortic valve predilatation 
9100BCL23 23mm	9100BCL26 26mm	<b>Ascendra balloon catheter</b> Radiopaque catheter markers ensure exact axial alignment of the balloon within the native aortic annulus 
96362 25ml	96362 25ml	<b>Atrion QL2530 inflation devices</b> Two inflation devices provided to optimize reliable, fast balloon catheter inflation and deflation for use with both the Ascendra balloon aortic valvuloplasty catheter and the Ascendra balloon catheter as shown above 
9100CR23 23mm	9100CR26 26mm	<b>Crimper</b> Single use, sterile crimpers conveniently provided for mounting the valve onto the balloon catheter 

26mm crimper with  
purple sizing gauges

23mm crimper with  
green sizing gauges

\*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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