

Indications for Use

Edwards SAPIEN™ Transcatheter Heart Valve, model 9000TFX, sizes 23mm and 26mm, and RetroFlex 3™ Delivery System, models 9120FS23 and 9120FS26

The Edwards SAPIEN Transcatheter Heart Valve, model 9000TFX, sizes 23mm and 26mm, and RetroFlex 3 Delivery System are indicated for transfemoral delivery in patients with severe aortic stenosis who have been determined by a cardiac surgeon to be inoperable for open aortic valve replacement and in whom existing co-morbidities would not preclude the expected benefit from correction of the aortic stenosis.

RetroFlex™ Balloon Catheter, models 9120BC20 and 9120BC23

The RetroFlex™ Balloon Catheter is indicated for valvuloplasty of a stenotic cardiac valve prior to implantation of an Edwards SAPIEN Transcatheter Heart Valve.

Crimper, models 9100CR23 and 9100CR26

The Crimper is indicated for use in preparing the Edwards SAPIEN Transcatheter Heart Valve for implantation.