LIFE IS DIFFERENT

CoreValve™ Evolut™ R
Transcatheter Aortic Valve Replacement (TAVR) Platform
BUILT ON A PROVEN FOUNDATION

The CoreValve™ System continues to demonstrate exceptional outcomes — and we’ve taken what we’ve learned from the design of that platform and applied it to the Evolut™ R System.

Supra-annular Valve Design
Self-expanding Nitinol Frame
Porcine Pericardial Tissue
Low Delivery Profile
The CoreValve™ Platform shows superior outcomes vs. surgery.¹

CoreValve™ system had significantly better valve performance over SAVR at all follow-up visits (P<0.001)¹

¹. CoreValve™ US Pivitol High Risk Trial 3-year Outcomes Presented at ACC 2016.
UNSURPASSED HEMODYNAMICS

Supra-annular valve design maximizes leaflet coaptation and promotes single digit gradients and large EOA’s.

7.5 mm Hg
single digit gradients

2.0 cm²
Large EOA
Supra-annular Valve | Optimizes coaptation in non-circular anatomy with supra-annular valve position

Annulus | Conforms to the native annulus

Exceptional Survival

98.8%
CONTROL DURING DEPLOYMENT

ACCURATE POSITIONING
1:1 response provides immediate feedback between the deployment knob and the movement of the capsule.

RECAPTURE AND REPOSITION
EnVeō™ R provides option to recapture and reposition for accurate placement.

1 Up to 80% deployment.
ACCESS MORE PATIENTS

BROADEST ANNULUS RANGE ON THE MARKET**
The only TAVR platform indicated to treat annulus up to 30 mm

17/18

23 mm Valve 26 mm Valve 29 mm Valve 34 mm Valve

30 mm

LOWEST DELIVERY PROFILE
The only TAVR system with a vessel indication down to 5.0 mm***

** Brodest annulus range based on CT derived diameters
† Measurement for TAV-in-SAV only.
** Evolut™ R 23, 26 and 29 mm valves. 34 mm valve minimum vessel indication ≥ 5.5 mm
Refrain from use of the catheter (e.g., use of the catheter) is not recommended. Retrieval of a partially deployed valve using the catheter may cause mechanical contact is made, the bioprosthesis cannot be advanced in the retrograde direction; if necessary, and the frame has only been deployed ≤2/3 of its length, the bioprosthesis can be withdrawn (repositioned) in the antegrade direction. However, use caution when moving the bioprosthesis in the antegrade direction. EnVeo R DCs Only: If a misalignment is detected, unseat the bioprosthesis and advance the catheter into the delivery sheath. Do not attempt to reload a damaged bioprosthesis. Do not load the bioprosthesis onto the catheter more than 2 times or after it has been utilized; the device may become contaminated. Use for access up to 16 Fr only. Do not use the trigger for deploying or recapturing because it could cause inaccurate placement of the bioprosthesis. EnVeo R Evolut US Only: If a misalignment is detected, unseat the bioprosthesis and advance the catheter (e.g., use of the catheter) is not recommended. Retrieval of the bioprosthesis from the patient is not recommended. Retrieval after the point of no recapture may cause mechanical failure of the delivery catheter system, aortic root damage, coronary artery damage, myocardial damage, vascular complications, prosthetic valve dysfunction (including device malposition), embolization, stroke, and/or emergent surgery. Do not attempt to retrieve or to recapture (EnVeo R DCs Only) a bioprosthesis if any one of the outflow struts is protruding from the coronary sinus or aorta. Do not use the catheter if the capsule becomes damaged during loading or, for surgical bioprosthetic valves, the manufacturer’s labeled inner diameter.<br><br>When using Model ENVEOR-US or transarterial access not able to accommodate a 20 Fr introducer sheath or the 16 Fr equivalent catheter, use a separate introducer sheath with a 16 Fr equivalent catheter (e.g., Medtronic) to perform the procedure under fluoroscopy. The safety and efficacy of a CoreValve or CoreValve Evolut R bioprosthesis implanted within the aortic root is dependent on effective coaptation; suture breaks or disruption; leaks; mal-sizing (prosthesis-patient mismatch); malposition (either too high or too low)/recapture), retrieval of the bioprosthesis from the patient is not recommended. Retrieval after the point of no recapture may cause mechanical failure of the delivery catheter system, aortic root damage, coronary artery damage, myocardial damage, vascular complications, prosthetic valve dysfunction (including device malposition), embolization, stroke, and/or emergent surgery. Do not attempt to retrieve or to recapture (EnVeo R DCs Only) a bioprosthesis if any one of the outflow struts is protruding from the coronary sinus or aorta. Do not use the catheter if the capsule becomes damaged during loading or, for surgical bioprosthetic valves, the manufacturer’s labeled inner diameter.<br><br>When using Model ENVEOR-US or transarterial access not able to accommodate a 20 Fr introducer sheath or the 16 Fr equivalent catheter, use a separate introducer sheath with a 16 Fr equivalent catheter (e.g., Medtronic) to perform the procedure under fluoroscopy. The safety and efficacy of a CoreValve or CoreValve Evolut R bioprosthesis implanted within the aortic root is dependent on effective coaptation; suture breaks or disruption; leaks; mal-sizing (prosthesis-patient mismatch); malposition (either too high or too low)/recapture), retrieval of the bioprosthesis from the patient is not recommended. Retrieval after the point of no recapture may cause mechanical failure of the delivery catheter system, aortic root damage, coronary artery damage, myocardial damage, vascular complications, prosthetic valve dysfunction (including device malposition), embolization, stroke, and/or emergent surgery. Do not attempt to retrieve or to recapture (EnVeo R DCs Only) a bioprosthesis if any one of the outflow struts is protruding from the coronary sinus or aorta. Do not use the catheter if the capsule becomes damaged during loading or, for surgical bioprosthetic valves, the manufacturer’s labeled inner diameter.<br><br>When using Model ENVEOR-US or transarterial access not able to accommodate a 20 Fr introducer sheath or the 16 Fr equivalent catheter, use a separate introducer sheath with a 16 Fr equivalent catheter (e.g., Medtronic) to perform the procedure under fluoroscopy. The safety and efficacy of a CoreValve or CoreValve Evolut R bioprosthesis implanted within the aortic root is dependent on effective coaptation; suture breaks or disruption; leaks; mal-sizing (prosthesis-patient mismatch); malposition (either too high or too low)/recapture), retrieval of the bioprosthesis from the patient is not recommended. Retrieval after the point of no recapture may cause mechanical failure of the delivery catheter system, aortic root damage, coronary artery damage, myocardial damage, vascular complications, prosthetic valve dysfunction (including device malposition), embolization, stroke, and/or emergent surgery. Do not attempt to retrieve or to recapture (EnVeo R DCs Only) a bioprosthesis if any one of the outflow struts is protruding from the coronary sinus or aorta. Do not use the catheter if the capsule becomes damaged during loading or, for surgical bioprosthetic valves, the manufacturer’s labeled inner diameter.<br><br>When using Model ENVEOR-US or transarterial access not able to accommodate a 20 Fr introducer sheath or the 16 Fr equivalent catheter, use a separate introducer sheath with a 16 Fr equivalent catheter (e.g., Medtronic) to perform the procedure under fluoroscopy. The safety and efficacy of a CoreValve or CoreValve Evolut R bioprosthesis implanted within the aortic root is dependent on effective coaptation; suture breaks or disruption; leaks; mal-sizing (prosthesis-patient mismatch); malposition (either too high or too low)/recapture), retrieval of the bioprosthesis from the patient is not recommended. Retrieval after the point of no recapture may cause mechanical failure of the delivery catheter system, aortic root damage, coronary artery damage, myocardial damage, vascular complications, prosthetic valve dysfunction (including device malposition), embolization, stroke, and/or emergent surgery. Do not attempt to retrieve or to recapture (EnVeo R DCs Only) a bioprosthesis if any one of the outflow struts is protruding from the coronary sinus or aorta. Do not use the catheter if the capsule becomes damaged during loading or, for surgical bioprosthetic valves, the manufacturer’s labeled inner diameter.<br><br>When using Model ENVEOR-US or transarterial access not able to accommodate a 20 Fr introducer sheath or the 16 Fr equivalent catheter, use a separate introducer sheath with a 16 Fr equivalent catheter (e.g., Medtronic) to perform the procedure under fluoroscopy. The safety and efficacy of a CoreValve or CoreValve Evolut R bioprosthesis implanted within the aortic root is dependent on effective coaptation; suture breaks or disruption; leaks; mal-sizing (prosthesis-patient mismatch); malposition (either too high or too low)/recapture), retrieval of the bioprosthesis from the patient is not recommended. Retrieval after the point of no recapture may cause mechanical failure of the delivery catheter system, aortic root damage, coronary artery damage, myocardial damage, vascular complications, prosthetic valve dysfunction (including device malposition), embolization, stroke, and/or emergent surgery. Do not attempt to retrieve or to recapture (EnVeo R DCs Only) a bioprosthesis if any one of the outflow struts is protruding from the coronary sinus or aorta. Do not use the catheter if the capsule becomes damaged during loading or, for surgical bioprosthetic valves, the manufacturer’s labeled inner diameter.<br><br>When using Model ENVEOR-US or transarterial access not able to accommodate a 20 Fr introducer sheath or the 16 Fr equivalent catheter, use a separate introducer sheath with a 16 Fr equivalent catheter (e.g., Medtronic) to perform the procedure under fluoroscopy. The safety and efficacy of a CoreValve or CoreValve Evolut R bioprosthesis implanted within the aortic root is dependent on effective coaptation; suture breaks or disruption; leaks; mal-sizing (prosthesis-patient mismatch); malposition (either too high or too low)/recapture), retrieval of the bioprosthesis from the patient is not recommended. Retrieval after the point of no recapture may cause mechanical failure of the delivery catheter system, aortic root damage, coronary artery damage, myocardial damage, vascular complications, prosthetic valve dysfunction (including device malposition), embolization, stroke, and/or emergent surgery. Do not attempt to retrieve or to recapture (EnVeo R DCs Only) a bioprosthesis if any one of the outflow struts is protruding from the coronary sinus or aorta. Do not use the catheter if the capsule becomes damaged during loading or, for surgical bioprosthetic valves, the manufacturer’s labeled inner diameter.<br><br>When using Model ENVEOR-US or transarterial access not able to accommodate a 20 Fr introducer sheath or the 16 Fr equivalent catheter, use a separate introducer sheath with a 16 Fr equivalent catheter (e.g., Medtronic) to perform the procedure under fluoroscopy. The safety and efficacy of a CoreValve or CoreValve Evolut R bioprosthesis implanted within the aortic root is dependent on effective coaptation; suture breaks or disruption; leaks; mal-sizing (prosthesis-patient mismatch); malposition (either too high or too low)/recapture), retrieval of the bioprosthesis from the patient is not recommended. Retrieval after the point of no recapture may cause mechanical failure of the delivery catheter system, aortic root damage, coronary artery damage, myocardial damage, vascular complications, prosthetic valve dysfunction (including device malposition), embolization, stroke, and/or emergent surgery. Do not attempt to retrieve or to recapture (EnVeo R DCs Only) a bioprosthesis if any one of the outflow struts is protruding from the coronary sinus or aorta. Do not use the catheter if the capsule becomes damaged during loading or, for surgical bioprosthetic valves, the manufacturer’s labeled inner diameter.