

CONFIDENCE DELIVERED.

INTERNATIONAL
CAUTION: For distribution
only in markets where
CoreValve Evolut R has been
approved. Non destiné au
marché français.

CoreValve™ Evolut™ R
Transcatheter Aortic Valve
Implantation (TAVI) System

Medtronic
Further, Together

BUILT ON A PROVEN FOUNDATION

DRIVING THE FUTURE OF TAVI

In our pursuit of meaningful innovation, we discovered breakthrough advancements are needed — for you and your patients. You guided us with 1,000 hours of collaboration. This discovery and collaboration have combined to bring us to today — the start of something new in TAVI.

CE Pivotal

ADVANCE

US Pivotal
-Extreme Risk

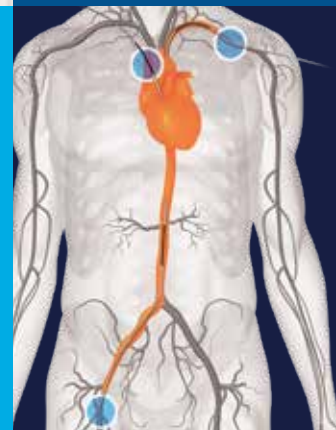
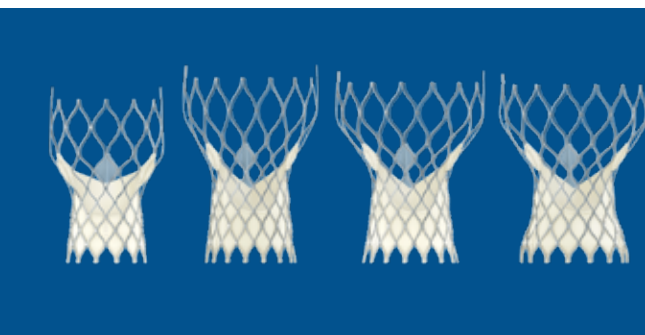
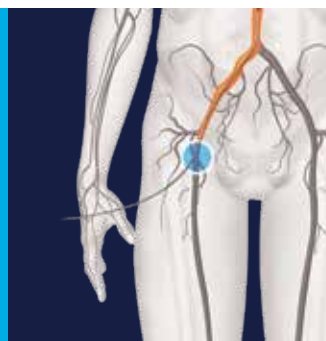
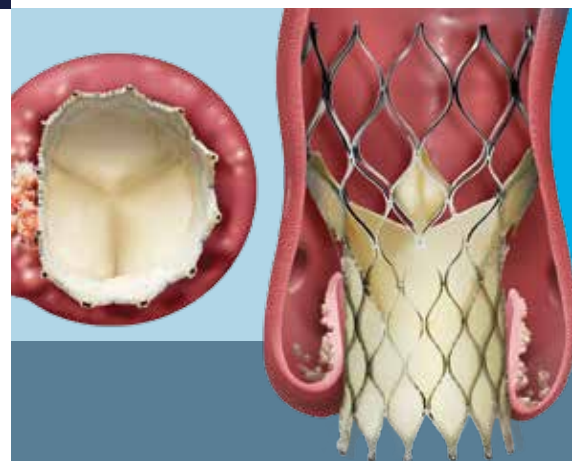
US Pivotal
-High Risk

Japan

SURTAVI

CoreValve
Evolut R CE

CoreValve
Evolut R US



ACCESS & PROFILE DELIVERED.

14Fr-Equivalent System with InLine™ Sheath
Improves Access¹ and Reduces Risk of Major
Vascular Complications²

THE ONLY SYSTEM
INDICATED
DOWN TO 5.0MM
VESSEL DIAMETER

5mm 14Fr^{equivalent}

4FR REDUCTION IN DELIVERY PROFILE

CoreValve
System

Evolut R
System

with 18Fr
Cook Sheath

with 14Fr-Equivalent
InLine™ Sheath

18Fr

18Fr

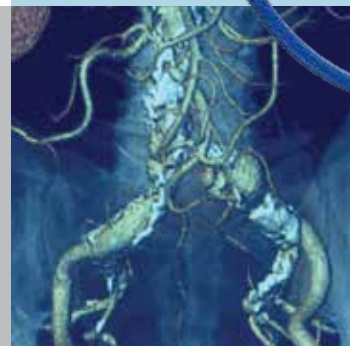
22Fr (OD)

True 18Fr (OD)

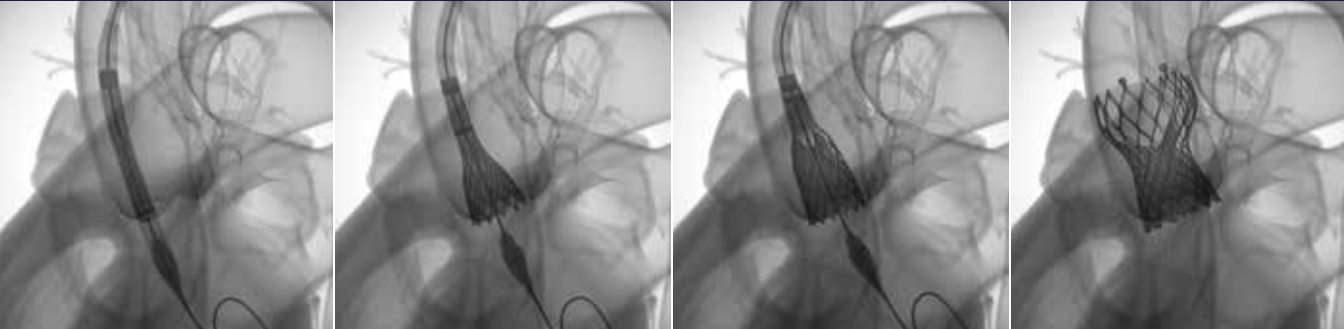
Drawn to scale. Not actual French sizes.

**THE LOWEST
DELIVERY PROFILE
FOR ALL VALVE SIZES
WITH 14FR
EQUIVALENT SYSTEM**

Larger sheath size has been shown
to increase the rate of major vascular
complications² and mortality.³

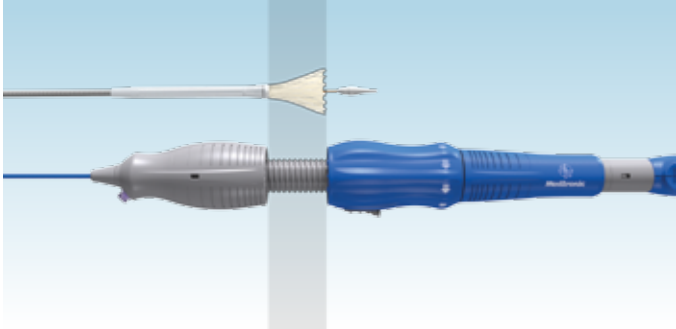


CONTROL & ACCURACY DELIVERED.



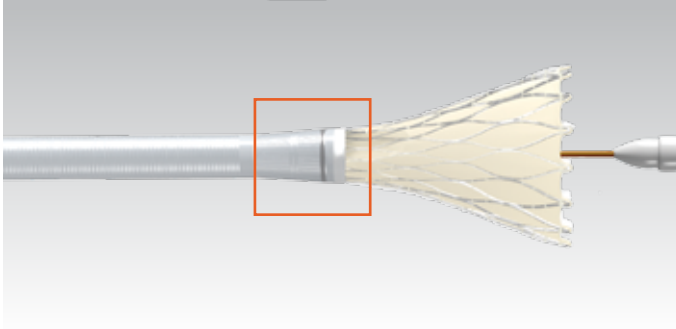
For added assurance of accurate placement, the EnVeo™ R delivery system provides the option to fully recapture and reposition* the valve.

Positioning accuracy is associated with reduced procedural complications, including reduced rates of PVL and conduction disturbances.⁴



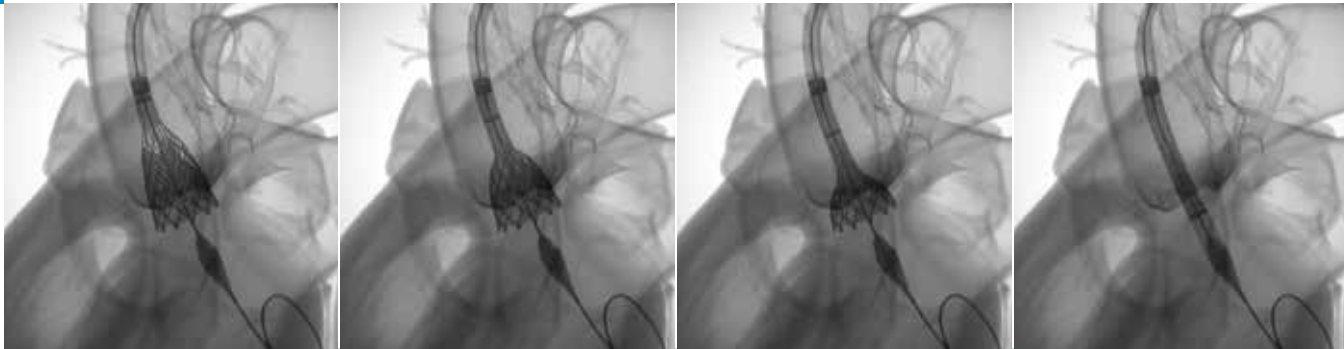
1:1 Response

Response between the catheter handle and the deployment of the valve clearly demonstrates no lag in the delivery system.



Self-Centering

Capsule flare and flexible catheter design enable uniform and controlled valve expansion and self-centering of the valve in the annulus.



Valve positioned too deep

Recapture begins

Partially recaptured

Valve fully recaptured

* Up to ~80% deployment. Medtronic Data on File.

HEMODYNAMICS & PERFORMANCE DELIVERED.

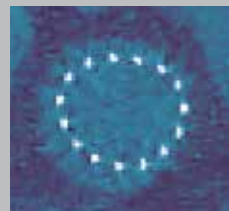
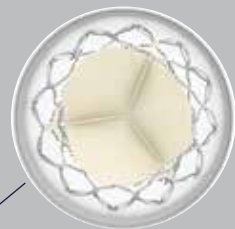
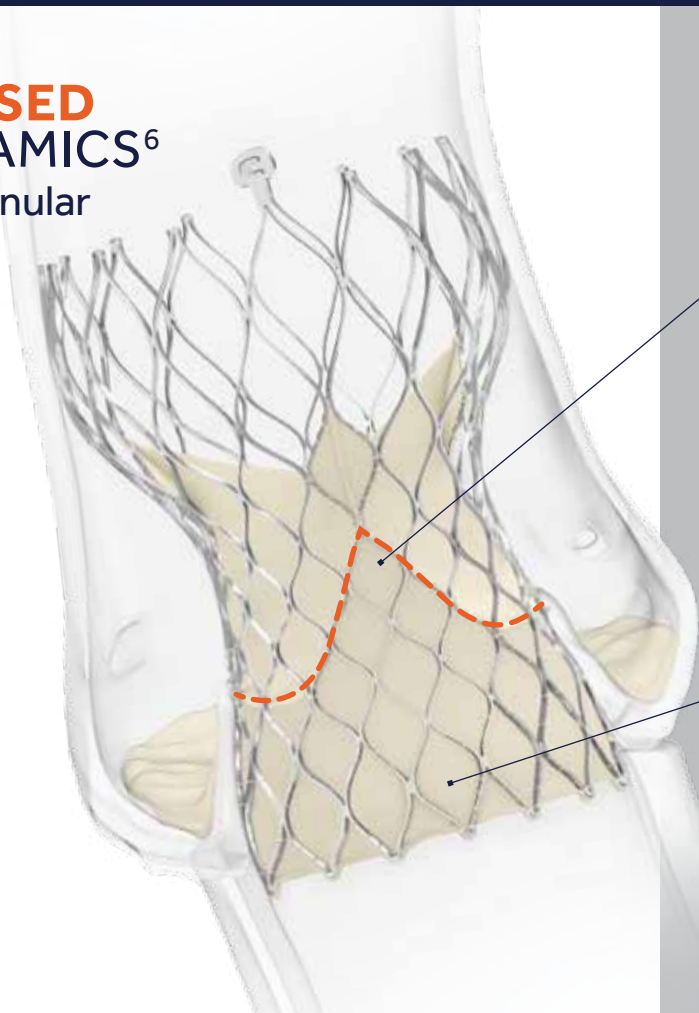
Reduction in significant paravalvular leakage is associated with increased survival.⁵

**UNSURPASSED
HEMODYNAMICS⁶**
with a supra-annular
valve design

8.1mm Hg
Single digit gradients

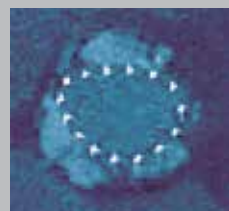
1.9 cm²
Large EOA

*CoreValve Evolut R CE Study
30-Day Results.*



Supra-annular Valve

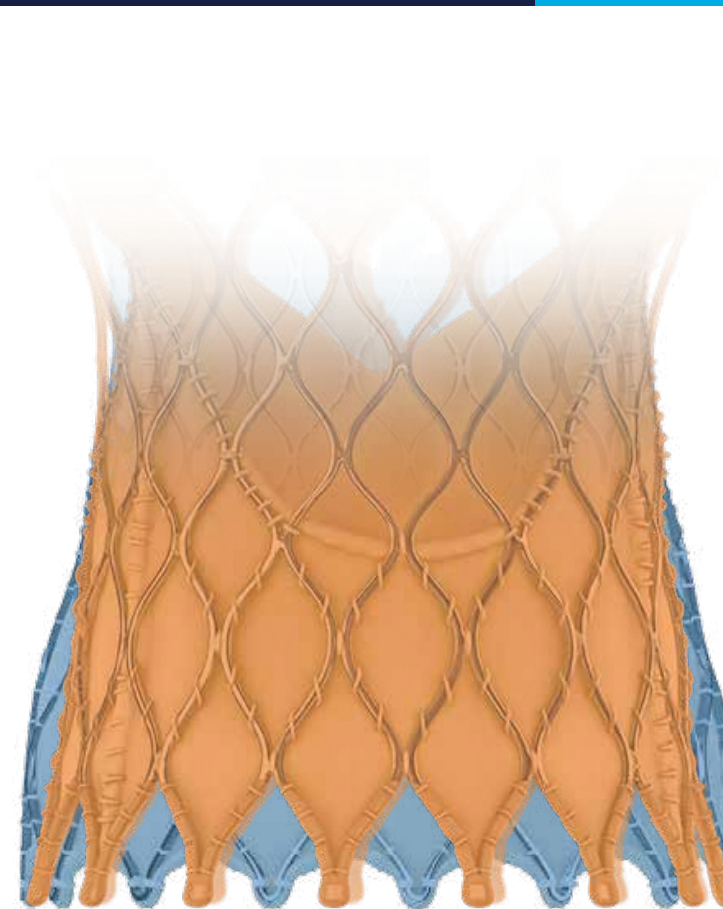
Optimizes coaptation in non-circular anatomy with supra-annular valve position



Annulus

Conforms to the native annulus

CT Image Source: PPT de Jaegere, C.J. Schultz, Thoraxcenter, Erasmus University, Rotterdam, The Netherlands.



PERFORMANCE THAT MATTERS

Deliberate design to improve clinical outcomes

ENHANCED SEALING

Increased Oversizing

Sizing optimized for annulus diameter range and implant depth.

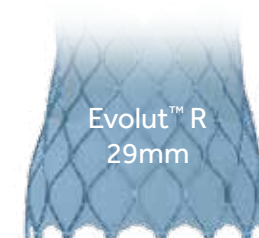
More Consistent Radial Force Across the Annulus Diameter

Evolut™ R Nitinol frame provides consistent radial force for improved sealing and PVL performance.

Extended Sealing Skirt



CoreValve™
29mm



Evolut™ R
29mm

TOGETHER
WE ARE
BUILDING
THE FUTURE
OF TAVI



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DELIVERED.

REFERENCES:

1. Medtronic, Inc. IFU M054712T001.
2. Sheath to Femoral Artery Ratio (SFAR) greater than 1.05 predicted higher rates of VARC major vascular complications. Hayashida K, et al. Transfemoral aortic valve implantation. JACC Intv 2011;4(8):851-8.
3. Genereux P, et al. Vascular complications after transcatheter aortic valve replacement: insights from the PARTNER (Placement of Aortic Transcatheter Valve) trial. JACC 2012;60(12):1043-52.
4. Tchetché D, et al. Update on the need for a permanent pacemaker after transcatheter valve implantation using the CoreValve® AccuTrak™ system. EuroIntervention 2012 Sep; 8(5):556-62.
5. Popma J, et al. Transcatheter aortic valve replacement using a self-expanding bioprosthesis in patients with severe aortic stenosis at extreme risk for surgery. JACC 2014;63(19):1972-81.
6. Data on File September 17, 2015.

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Refer to Instructions for Use for a complete list of warnings, precautions and contraindications.

medtronic.eu // CoreValveEvolutR.com

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