

Evolut R:
La nuova frontiera delle valvole
transcatetere

Confidence. Delivered.

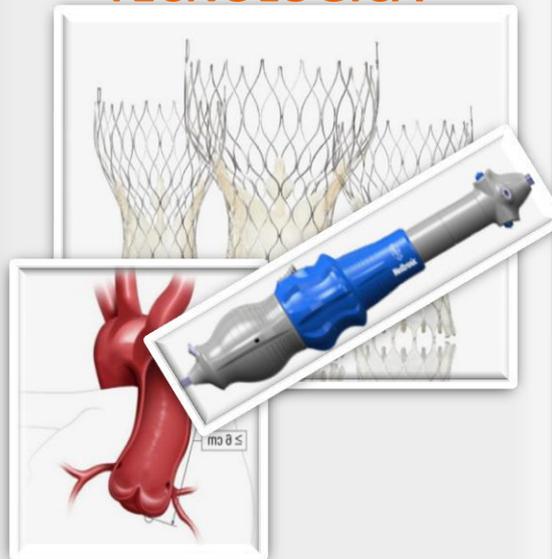
Programma valvole transcatetere



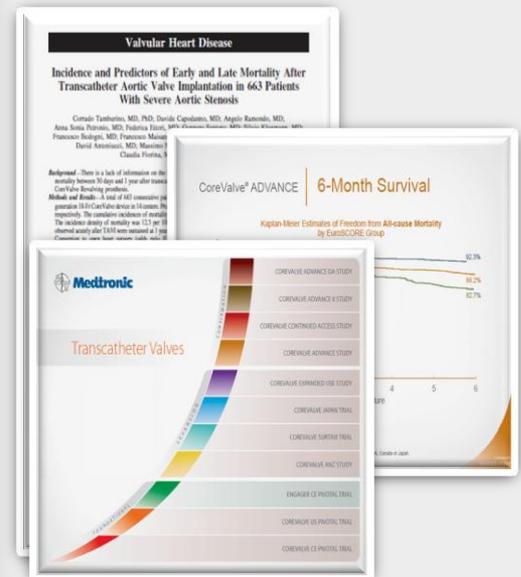
ESPERIENZA



INNOVAZIONE TECNOLOGICA



EVIDENZA CLINICA



ESPERIENZA

10 anni dal primo impianto (luglio 2004)



Dr E Grube, Dr JC Laborde

Delivery System: Sviluppo tecnico



2004

2005

2006



Piazza, Serruys, DeJaegere

Innovazione tecnologica



2000

2007

2008

2009

2010

2011

2012

Valvola



Melody



18 FR

Accesso e pazienti

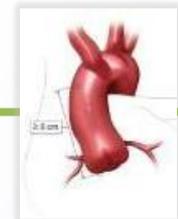


Transfemorale



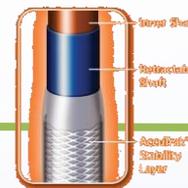
Succlavia

Aortico diretto



Posizionamento facilitato

AccuTrak



Miglior efficacia

31mm



Innovazione tecnologica



2012

2013

2014

Valvola

Engager



FDA Approval



Accesso e
pazienti

ViV



Confida
Wire



Posizionamento
facilitato

Miglior
efficacia

Evolut
23mm

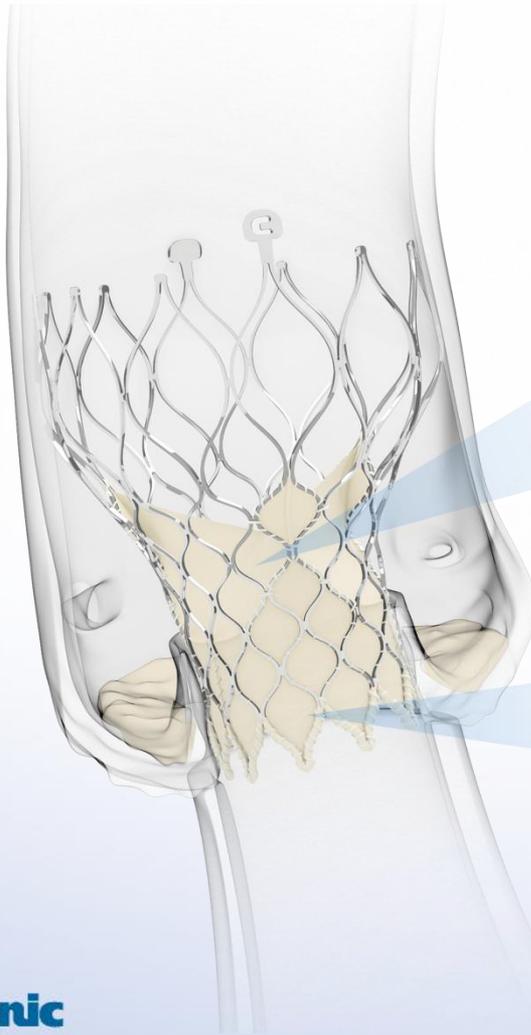


AOA

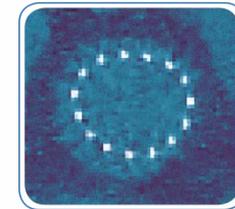
EvolutR



Evolut R: costruita sulla piattaforma CoreValve[®] – frame in nitinolo autoespandibile e disegno sovra-anulare

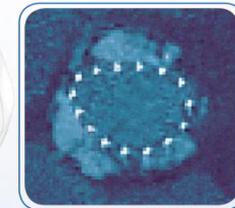
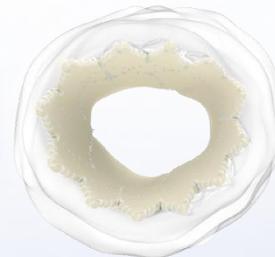


Supra-annular Valve



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

Annulus

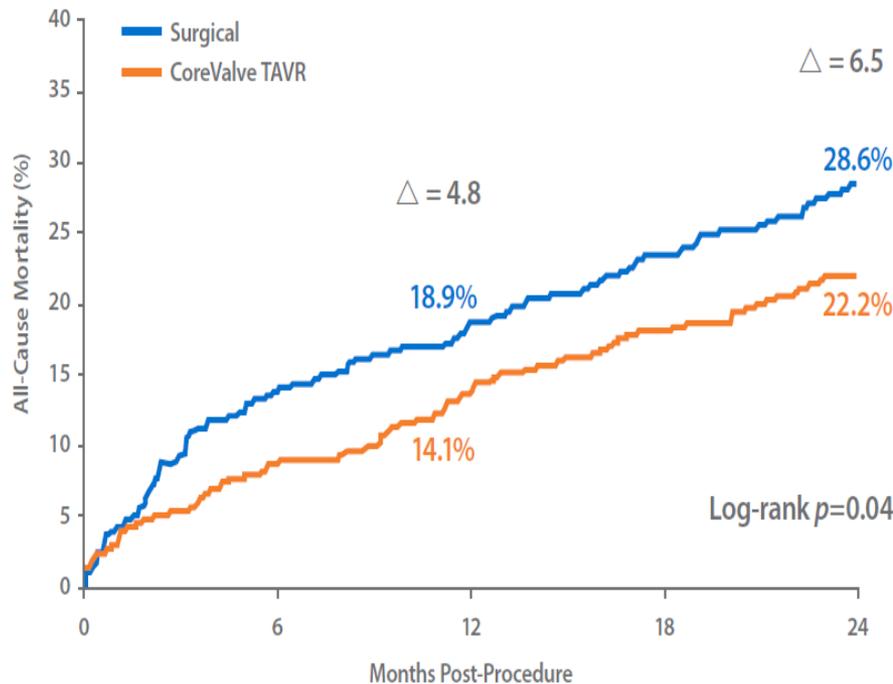


Conforms to the native annulus

CoreValve US Pivotal Alto rischio: Messaggi chiave

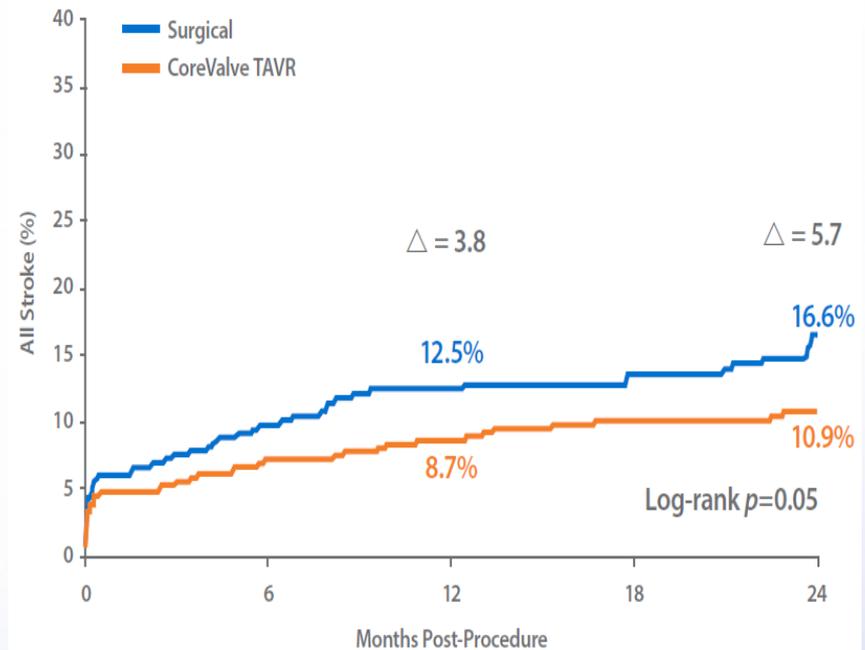


- Superior Survival at 2-Years



The CoreValve System demonstrates a low all-cause mortality rate that outperforms the standard of care at 2 years.

Lower Stroke Rate



The CoreValve System showed a lower rate of all stroke ($p=0.05$) and a similar rate of major stroke ($p=0.25$) vs. SAVR at 2 years.

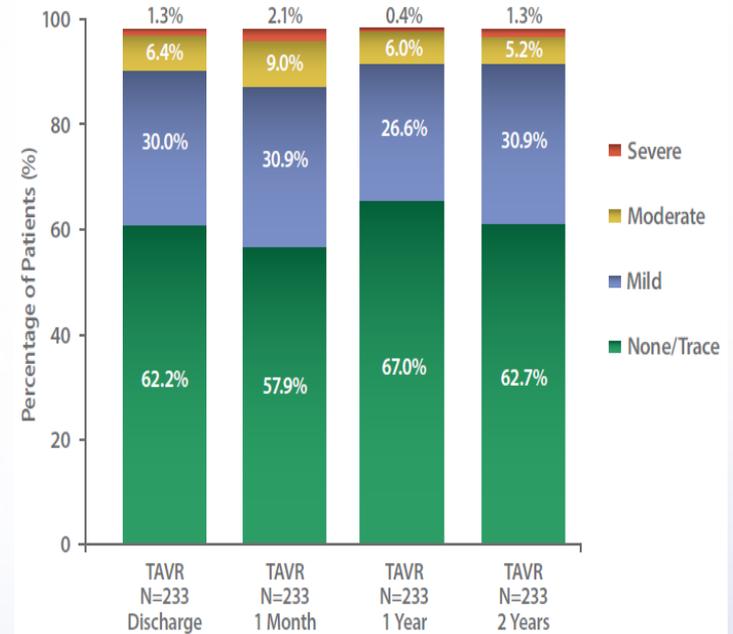
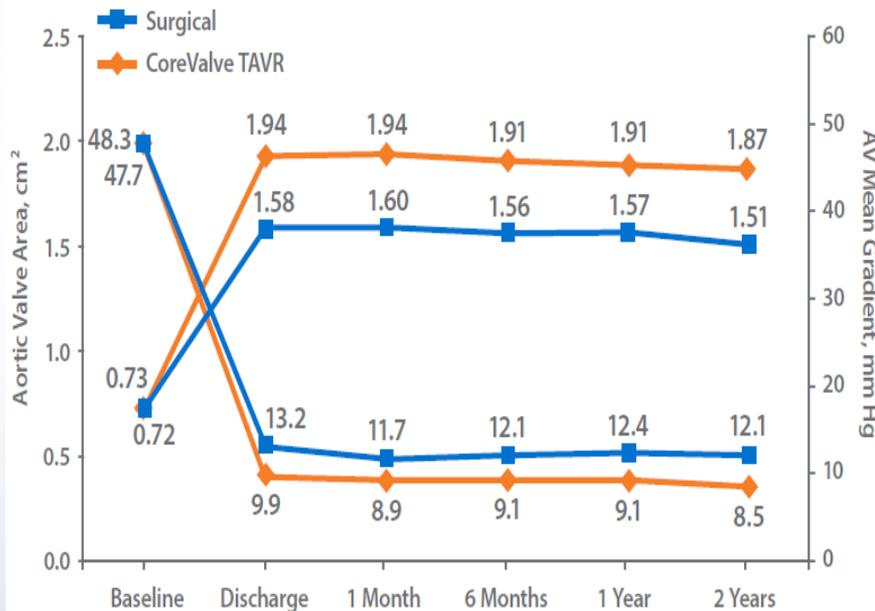
CoreValve US Pivotal Alto rischio: Messaggi chiave



- Superior Hemodynamics

Low Rates of PVL

TAVR had significantly better valve performance over SAVR at all follow-up visits ($p < 0.001$)



Supra-annular design optimizes orifice area, delivering low single-digit gradients that are superior to SAVR at each follow-up visit.

The CoreValve Nitinol frame conforms and seals to the annulus, maintaining a consistently low rate of moderate/severe PVL between 1 and 2 years.

Clinical need

1. Basso rapporto tra diametro esterno del delivery e femorale (SFAR)

Riduzione rischio complicanze vascolari maggiori

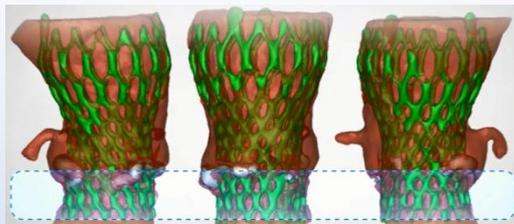
2. Accuratezza nel posizionamento

Fondamentale per migliorare gli outcome clinici (PVL, disturbi del ritmo,...)

3. Sealing a livello dell'annulus

Ridurre il PVL

4. Facilità di utilizzo



CT images courtesy of Dr. Piazza and Prof. Lange, German Heart Center, Munich Germany

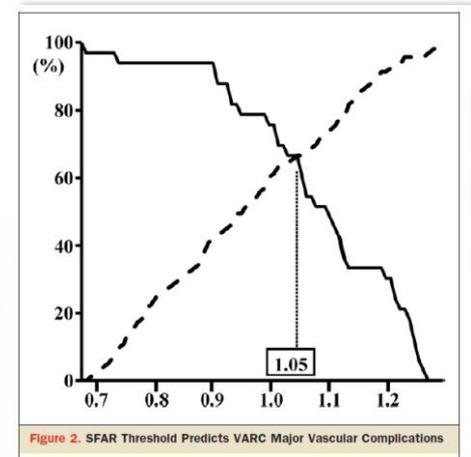
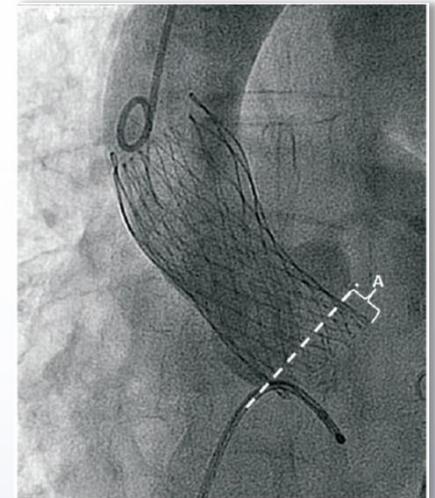


Figure 2. SFAR Threshold Predicts VARC Major Vascular Complications

(Hayashida K., Lefevre T., Chevalier B.; et al. Transfemoral Aortic Valve Implantation; New Criteria to Predict Vascular Complications, J Am Coll Cardiol Intv 4 2011 851-858)



(TcheTche, et. al. – EuroIntervention 2012)

Ogni singolo componente del sistema EvolutR
è stato ottimizzato



Catheter Delivery System

14Fr-equivalent profile



Loading System



Transcatheter Valve



#1: il più basso profilo sul mercato, equivalente
a 14Fr con introduttore InLine™

Il più basso profilo di delivery, equivalente a 14Fr, con introduttore InLine™



Riduzione del profilo di 4Fr

Migliora l'accesso e riduce i rischi di complicanze valvolari maggiori

CoreValve®

Evolut™ R

with 18Fr

with 14Fr-Equivalent

**Indicato per arterie
con diametro uguale
o superiore a 5 mm**

D)

18Fr
OD

(14FR-Equivalent)



Confidence. Delivered.

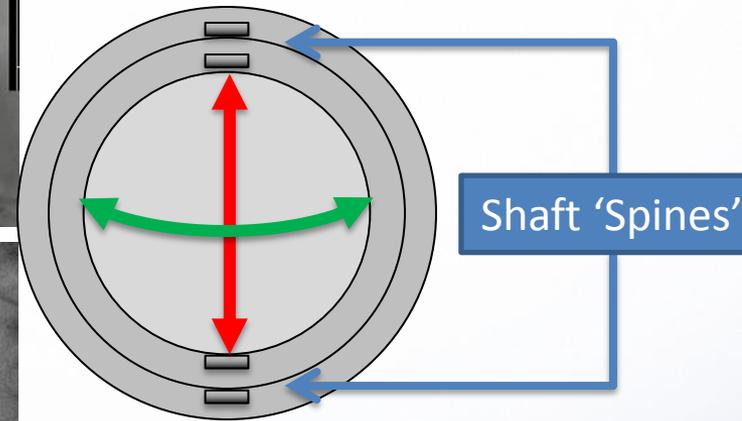
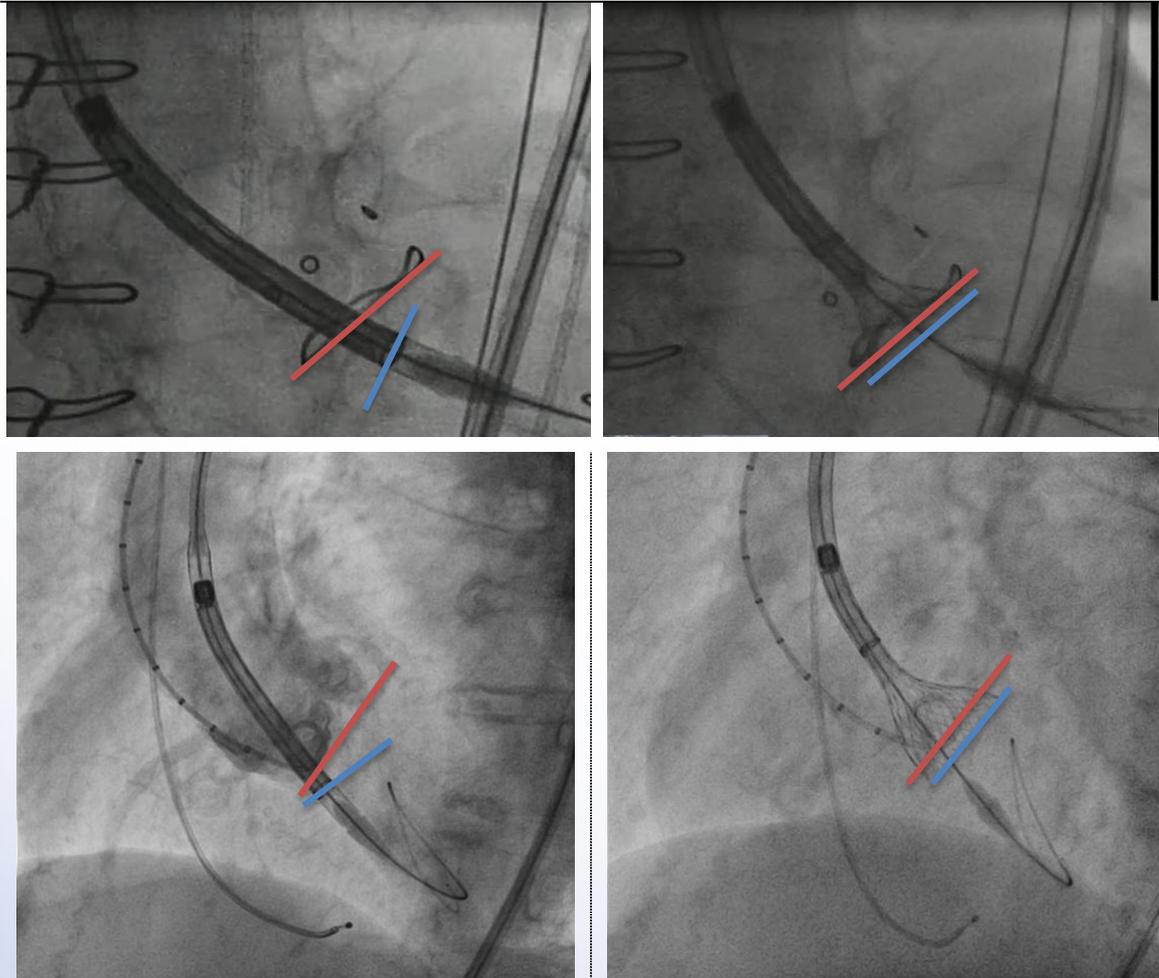


#2: Disegnata per posizionamento corretto al primo tentativo con possibilità di ricattura

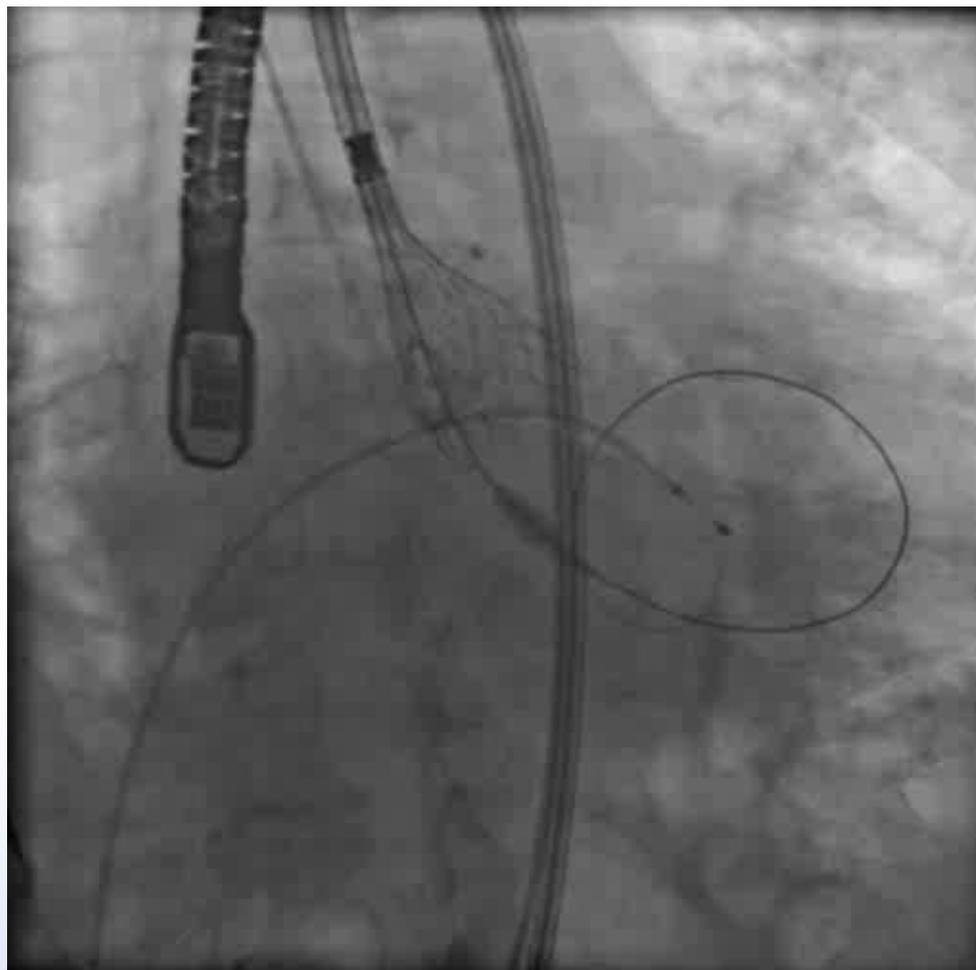
Risposta 1:1



Self-Centering



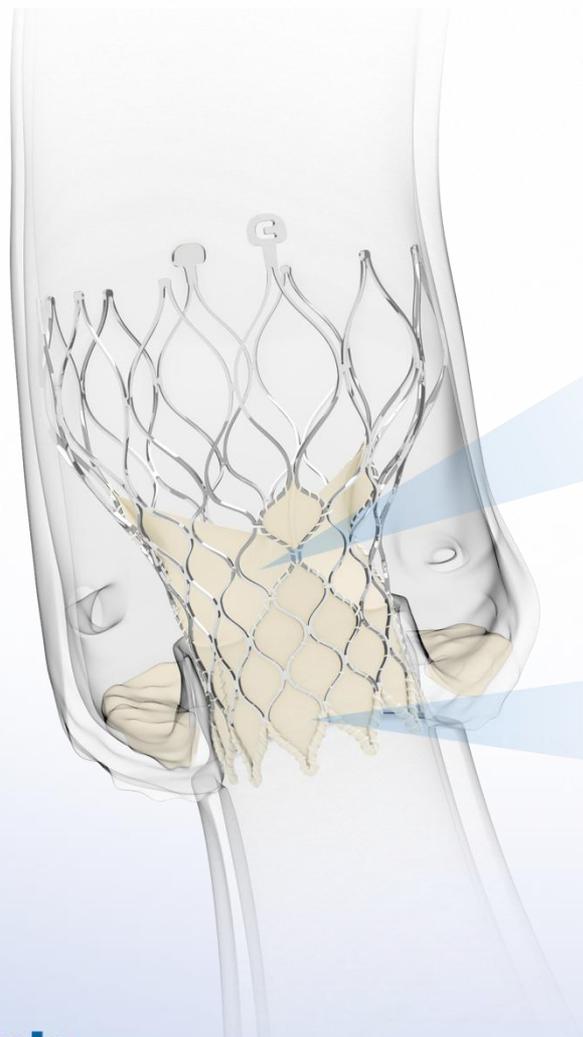
EnVeo R permette ricattura e riposizionamento



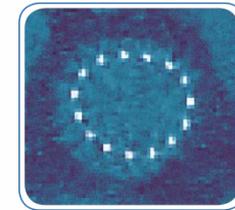


#3: performance della valvola eccezionali e PVL ridotto

Performance della valvola eccezionali: Evolut R mantiene il design sovra-anulare

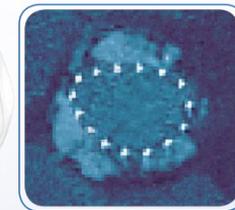


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Annulus

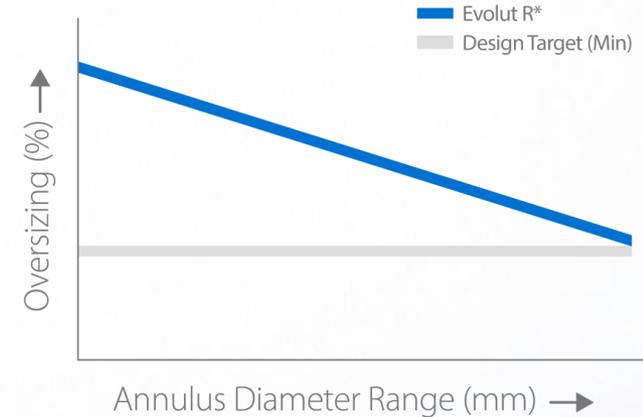
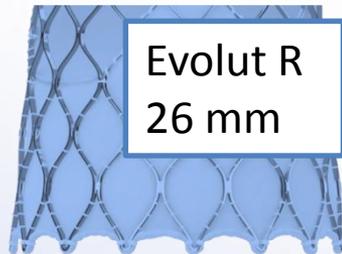
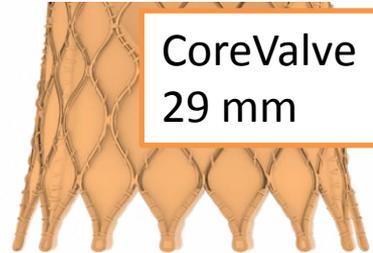
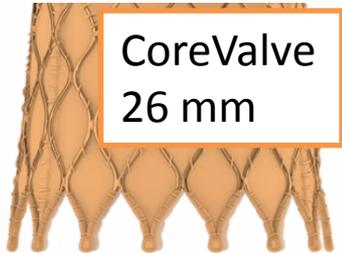


Conforms to the native annulus

Confronto dell' Inflow CoreValve

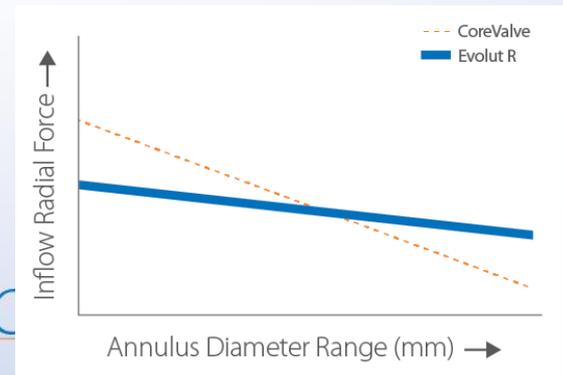


Ottimizzazione del cover index
Ottimizzazione del sizing per un vasto range di annulus

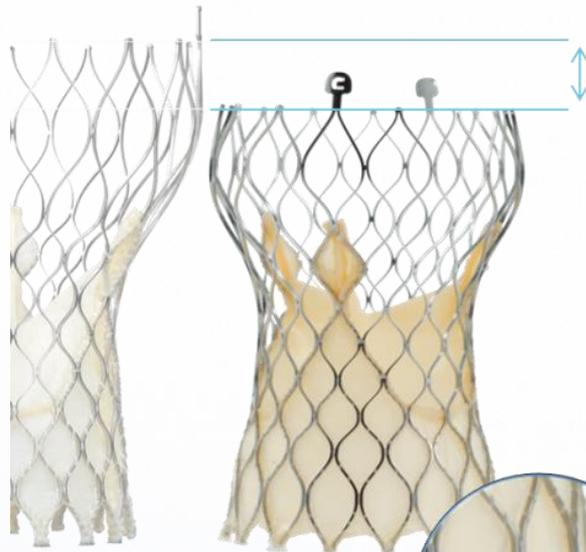


* Represents CoreValve Evolut R 23, 26, 29mm transcatheter valve

Forza radiale consistente
contribuisce ad un migliore sealing sui diversi diametri



PVL ridotto: estensione della gonna



Outflow accorciato



Gonna estesa*

Landing zone più lunga, sealing maggiore



Messaggi chiave

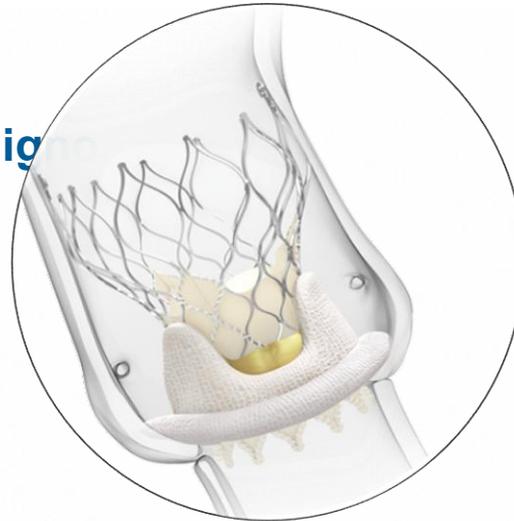
- #1: il più basso profilo sul mercato, equivalente a 14Fr con introduttore InLine™
- #2: Disegnata per posizionamento corretto al primo tentativo con possibilità di ricattura
- #3: performance della valvola eccezionali e PVL ridotto

Indicazione per il Valve-in-Valve

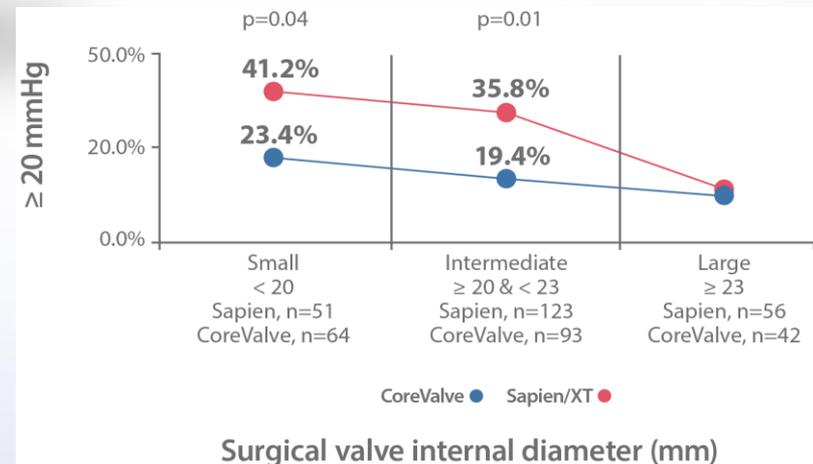


Design Sovra-Annulare massimizza il flusso sabguig

Orifizio valvolare potenzialmente 25%
superiore



Bassi gradienti Post- Procedural



1. Medtronic data on file. Bench testing comparison between CoreValve and Sapien XT in surgical bioprosthesis.

2. Dvir D, Webb JG, Bleiziffer S, et al. Transcatheter aortic valve implantation in failed bioprosthetic surgical valves. JAMA 2014;312(2):162-170. doi:10.1001/jama.2014.7246



Dati clinici a 30 giorni – ACC 2015

0%

**All-cause mortality / All stroke
Annular rupture* / Coronary o
bstruction*
Valve embolization***

Moderate or severe PVL

3.4%

11.7%

**Permanent
pacemaker
implantation**



Thank You!
