# Operate with the Facts

An Aortic Valve Comparison: The Carpentier-Edwards PERIMOUNT Magna Ease pericardial aortic bioprosthesis vs. the Abbott Trifecta GT aortic bioprosthesis



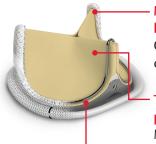


### Operate with confidence.



### **PERIMOUNT Valve Platform:** Proven Design

#### **PERIMOUNT valve design**



### Mathematically modeled, bioengineered design

Optimized for hemodynamics, durability and implantability

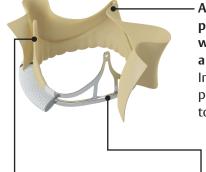
### Three independent bovine pericardial leaflets

Matched for thickness and elasticity to optimize stress distribution

#### Flexible cobalt-chromium alloy stent

Absorbs energy to reduce leaflet stress

#### Trifecta GT valve design



## A single bovine pericardial strip wrapped around a stent

Inherent variations in pericardial strip can lead to asymmetric leaflets

### External mounted leaflets

Risk of coronary obstruction following valve-in-valve procedures is as much as nine times higher in patients with bioprostheses with external mounted leaflets<sup>1</sup>

### Titanium band and stent

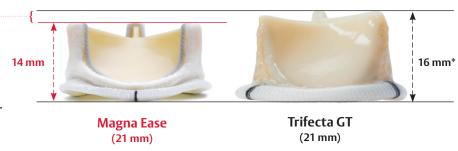
The Trifecta GT valve instructions for use state that the titanium valve stent is not designed as a flexible stent and that deformation of the stent may impair valve function<sup>2</sup>

### The Magna Ease valve has lower profile height for ease of implant

### 2 mm lower profile

Across all sizes

The Trifecta GT valve has the same profile height as the previous version, which is 2 mm higher than the Magna Ease valve across all sizes.



 ${\rm *Profile}\ height\ according\ to\ Instructions\ for\ Use$ 

The Magna Ease valve has a low profile designed to ease insertion through small incisions or aortic roots, ease aortotomy closure and maximize coronary ostia clearance.

### **PERIMOUNT Valve Platform:** Proven Long-term Durability

### The PERIMOUNT valve has more long-term clinical study publications than any other aortic bioprosthesis

### **PERIMOUNT valve design**

20+
years of published clinical durability data



### Trifecta valve design

**6**years of published clinical data

### PERIMOUNT valve design: 30 publications with 10+ years follow-up



Trifecta valve: **0 publications** with **7+ years** follow-up

### After more than 1 billion cycles, the Magna Ease valve still performs like new.<sup>33</sup>

The Magna Ease valves demonstrated excellent durability after the equivalent of 25 years in simulated in vitro wear, with hydrodynamic performance similar to that of a new valve.



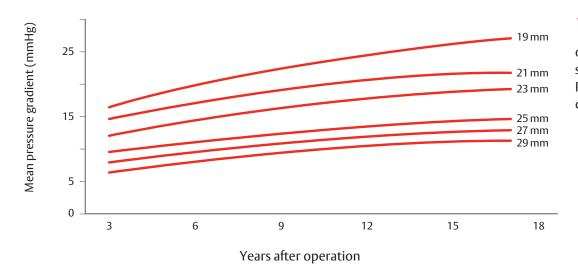
New valve



Billion cycled valve

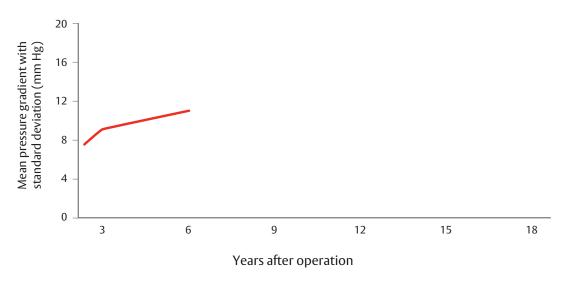
### **PERIMOUNT Valve Platform:** Excellent and Stable Hemodynamics

#### PERIMOUNT valve design has proven long-term hemodynamic stability<sup>34</sup>



### 17 years of hemodynamic stability data with PERIMOUNT valve design

### Trifecta average mean gradients increase over 6 years<sup>35</sup>



# 6 years A study by Goldman, et al., o

Goldman, et al., of the Trifecta valve indicated a 43% increase in mean gradients.<sup>36</sup>

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### PERIMOUNT Valve Platform: The Surgeons' Choice



After examining the facts, it is no wonder that 70% of cardiac surgeons would choose an Edwards tissue valve for themselves or a close family member.\*

\*Based on a double-blind survey of 255 U.S. cardiac surgeons conducted in Q4 2014. Data on file.

#### **Brief summary: Aortic Bioprostheses**

**Indications:** For use in patients whose aortic valvular disease warrants replacement of their natural or previously placed prosthetic valve. Contraindications: Do not use if surgeon believes it would be contrary to the patient's best interests.

Complications and side effects: Stenosis, regurgitation, endocarditis, hemolysis, thromboembolism, valve thrombosis, nonstructural dysfunction, structural valve deterioration, anemia, arrhythmia, hemorrhage, transient ischemic attack/stroke, congestive heart failure, myocardial infarction, angina, any of which could lead to reoperation, explantation, permanent disability, and death. Warnings: Alternative therapies should be considered in the presence of conditions affecting calcium metabolism or when calcium containing chronic drug therapies are used, including children, adolescents, young adults, and patients on a high calcium diet or maintenance hemodialysis. Should be used with caution in the presence of severe systemic hypertension or when anticipated patient longevity is longer than the known longevity of the prosthesis.

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician. See the Instructions for Use for a full description of prescribing information.

