Freestyle™
Bioprosthesis

PHYSIOLOGIC FREESTYLE

Maximal blood flow, excellent durability and outcomes, from a valve designed to mimic nature.

Medtronic
Further, Together

The Freestyle™ bioprosthesis is our most physiologic surgical valve. Every aspect is meant to closely emulate the native aortic valve and offer comparable benefits. It is a great choice for younger, more active patients — and those with challenging anatomies — because of its excellent hemodynamics, durability, and patient outcomes.

The full root, stentless design of the Freestyle porcine bioprosthesis — based on more than 30 years of Medtronic tissue valve design improvements — can be used for full root, modified subcoronary, and complete subcoronary configurations.

Full Root

Complete Subcoronary

Modified Subcoronary

Freedom from explant due to SVD

83%

at 15 years[1]

Single-digit gradients out to

10

years[2]

OUR MOST PHYS

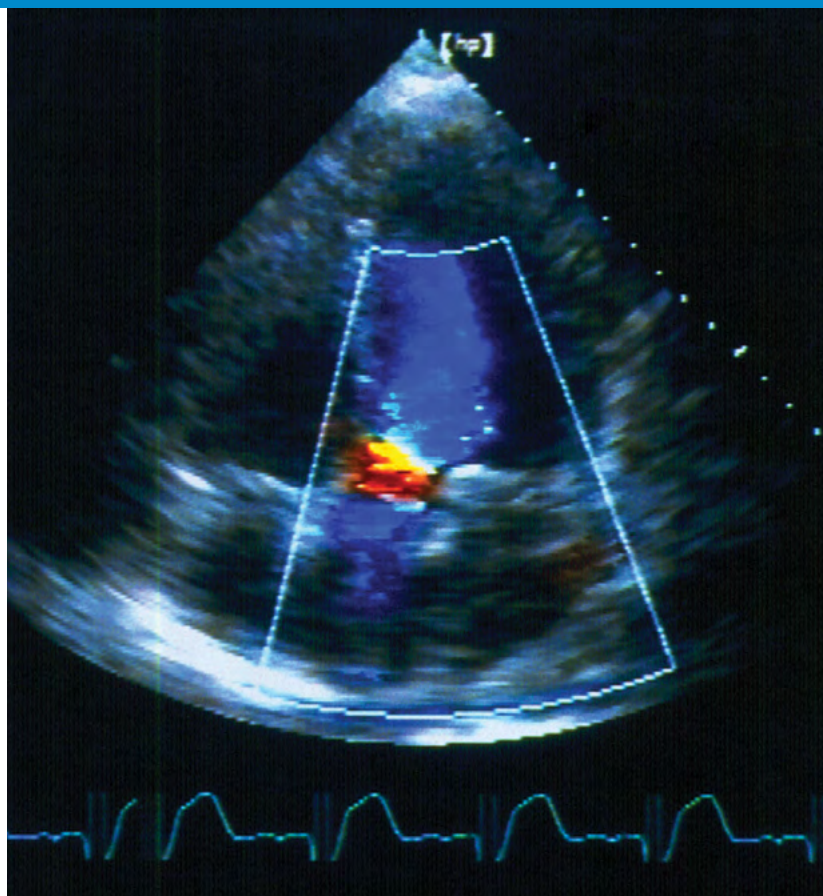
STENTLESS DESIGN

By closely mimicking human physiology, the Freestyle valve offers excellent hemodynamics — just like nature, with laminar flow and low gradients.

MAXIMUM BLOOD FLOW

The Freestyle valve is hemodynamically superior to stented[3] and mechanical[4] valves in the aortic position because it's stentless and has no sewing ring. This means you get:

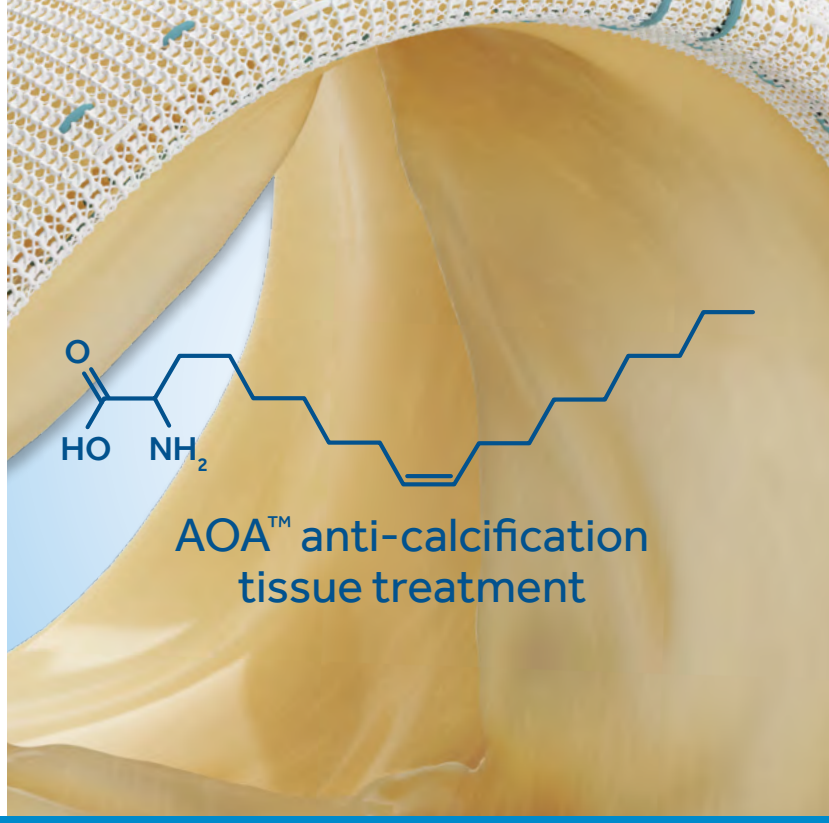
- Larger postoperative effective orifice areas (EOA)[3]
- Stable, single-digit gradients and EOAs at 10 years[2]



DURABILITY

Published clinical experience demonstrates impressive long-term performance in all age groups. Additional factors that may contribute to durability are:

- Proprietary AOA™ anti-calcification tissue treatment that mitigates calcification and protects the tissue*
- Physiologic Fixation process that minimizes the stress applied to the leaflets during fixation

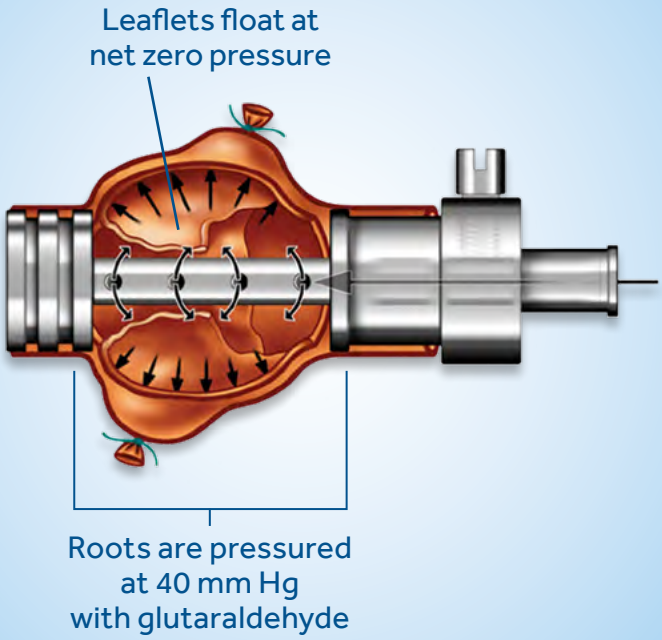


SIOLOGIC VALVE

ADVANCED TISSUE FIXATION

Our exclusive Physiologic Fixation process mitigates biomechanical failures and promotes long-term valve durability by:

- Improved preservation of valve structure and leaflet function, allowing it to function similar to a native valve
- Allowing leaflets to remain soft and flexible which protects the tissue from cyclic fatigue



*No clinical data is available which evaluates the long-term impact of the Physiologic Fixation process or the impact of AOA treatment in patients.

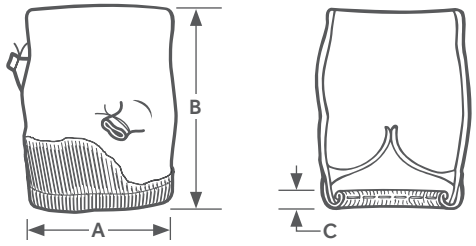
With our comprehensive portfolio of solutions for surgical and interventional approaches, **we support the lifetime management of your patients — every beat, every day.**

Medtronic and you.
Let's take healthcare Further, Together.

PRODUCT SPECIFICATIONS

Freestyle™ Full Root Bioprosthesis

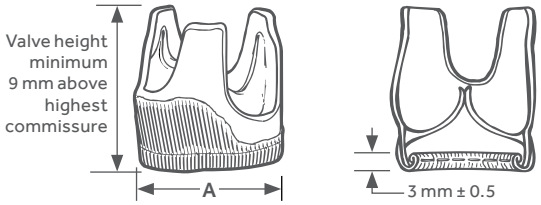
Order Number	Valve Size (± 0.5 mm)	Outside Diameter (+ 0.5 mm–0.0 mm)	Profile Height (± 2 mm)	Inner Cloth Height (± 0.5 mm)
		(A)	(B)	(C)
FR99519	19	19.0	30	3.0
FR99521	21	21.0	32	3.0
FR99523	23	23.0	32	3.0
FR99525	25	25.0	34	3.0
FR99527	27	27.0	34	3.0
FR99529	29	29.0	39 ± 3 mm	3.0
Freestyle Obturator Kit: 7990SET				
Freestyle Holder Handle: 7639				



Prestyled Freestyle™ Complete Subcoronary Bioprosthesis

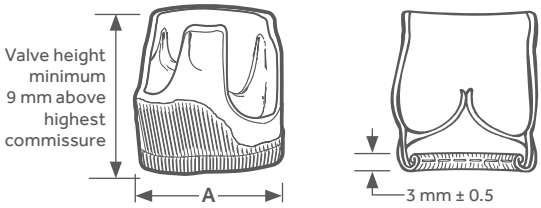
Order Number	Valve Size (± 0.5 mm)	Outside Diameter (+ 0.5 mm–0.0 mm)
		(A)
995CS19	19	19.0
995CS21	21	21.0
995CS23	23	23.0
995CS25	25	25.0
995CS27	27	27.0
995CS29*	29	29.0
Freestyle Obturator Kit: 7990 SET		
Freestyle Holder Handle: 7639		

*Note: This size is not approved in the U.S.



Prestyled Freestyle™ Modified Subcoronary Bioprosthesis

Order Number	Valve Size (± 0.5 mm)	Outside Diameter (+ 0.5 mm–0.0 mm)
		(A)
995MS19	19	19.0
995MS21	21	21.0
995MS23	23	23.0
995MS25	25	25.0
995MS27	27	27.0
995MS29	29	29.0



References

1. Freestyle Aortic Root Bioprosthesis 15-year Clinical Compendium. ©2016 Medtronic.
2. Freestyle Aortic Root Bioprosthesis 12-year Clinical Compendium. ©2007 Medtronic.
3. de Arenaza D, Lees B, Flather M, et al. Randomized comparison of stentless versus stented valves for aortic stenosis. *Circulation* 2005;112:2696-2702.
4. Silberman S, Shaheen J, Merin O, et al. Exercise hemodynamics of aortic prostheses: Comparison between stentless bioprostheses and mechanical valves. *Ann Thorac Surg* 2001;72:1217-21.

Freestyle Bioprosthesis Indications: For the replacement of malfunctioning native or prosthetic aortic valves with the option of aortic root replacement. **Contraindications:** None known. **Warnings/Precautions/Adverse Events:** Accelerated deterioration due to calcific degeneration of bioprosthesis may occur in: children, adolescents, young adults, and patients with altered calcium metabolism (e.g., chronic renal failure, hyperparathyroidism). Adverse events can include: cardiac dysrhythmias, death, endocarditis, hemolysis, hemorrhage, transvalvular or paravalvular leak, nonstructural dysfunction, structural deterioration, thromboembolism, valve thrombosis, or intracuspal hematoma.

Caution: Federal law (USA) restricts these devices to sale by or on the order of a physician.

For a listing of indications, contraindications, precautions, warnings, and potential adverse events, please refer to the Instructions for Use. For countries that use eIFUs, consult instructions for use at this website www.medtronic.com/manuals. Note: Manuals can be viewed using a current version of any major internet browser.

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