



MEDTRONIC OPEN PIVOT™

heart valves



Simply Quiet

Seize Simplicity with a design that provides a valve solution most patients cannot hear after implantation.



Medtronic Open Pivot™ AP360°
Supra-annular flanged cuff configuration for maximum flexibility, needle penetration and conformability.



Medtronic Open Pivot™ AP°
Supra-annular compact cuff configuration for excellent suturability and conformability.



Medtronic Open Pivot™ Standard
Intra-annular valve with generous, compliant cuff for exceptional implantability.

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So quiet only one in five patients is aware of their valve sound¹

In two one-year postoperative studies, 18.8% of Medtronic Open Pivot valve patients noticed their valve sound. "The results of interviews with patients showed that more than 80% of patients with ATS (Medtronic) valves could not hear the valve sounds... From these results, the ATS (Medtronic) valve is considered as an excellent prosthetic valve in terms of the quality of life it offers patients." - Sezai¹ (This quote is from the author's paper studying valve sound, it is speaking of improved quality of life as it specifically relates to heart valve sound.)

Gentle passive washing results in low levels of hemolysis and thromboembolic events^{2,3}

Continuous passive washing ensures complete washing of the pivot in both open and closed positions with gentle treatment of red blood cells.

Orifice design and unique leaflet movement result in excellent EOAs, even in small sizes⁴

Because of the unique leaflet placement, there is no need to manipulate leaflet motion by extending the orifice in any way. This allows for a single-plane orifice, providing ease of implantability. Its orifice of solid pyrolytic carbon and strengthening band of thin titanium provides large orifice-to-annulus ratios without compromising structural integrity.

Seize Simplicity

Simplicity clears the way to let you decide what's best. There are many patient considerations, but only one judgment call. Consider Medtronic's intuitive heart valve solutions in all your decisions.

seizesimplicity.com

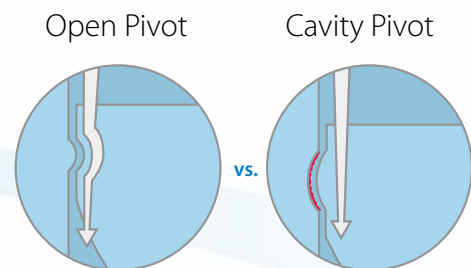
Risks: Certain complications may occur with heart valve procedures. The adverse events potentially associated with the use of mechanical heart valves include, cardiac arrhythmias, death, leaflet entrapment (impingement), endocarditis, hemolysis, anticoagulant-related hemorrhage, transvalvular or perivalvular leak, prosthesis thrombosis, structural deterioration, valve thromboembolism.

A fundamentally different design

- Unlike all other bileaflet valves, Medtronic Open Pivot valves have no recesses or cavities in the pivot area where potential thrombus can form.^{5,6}
- Continuous passive washing provides for gentle treatment of red blood cells and low levels of hemolysis and thromboembolic events.^{5,7}
- Unique axis of suspension provides an exceptionally efficient design resulting in leaflet movement responsive to physiological demands and excellent hydrodynamic performance.⁸
- Solid pyrolytic carbon orifice and strengthening band for thin yet strong orifice and large Geometric Orifice Areas (GOAs).
- Single plane orifice facilitates valve seating and implant regardless of suture technique.

Exceptional performance

- Remarkable thromboresistance⁴
- Excellent hemodynamics⁴
- Outstanding durability²
- Exceptional implantability
- Remarkably quiet¹

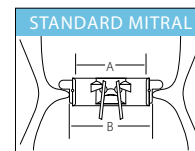
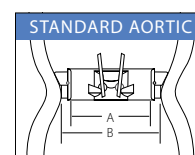


Open Pivot valves have no recesses or cavities where potential thrombus may form and minimize flow disruption and turbulence in pivot area.

Cavity pivot area provides opportunity for stasis—and relies on mechanical sweeping and high velocity leakage jets to function.

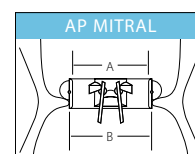
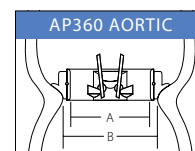
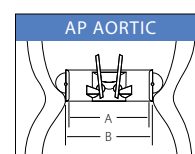
Medtronic Open Pivot™ Standard Heart Valve

	AORTIC					MITRAL				
	Valve Size (mm)	Standard Model Number	Tissue Annulus Diameter (B) (mm)	Orifice Inner Diameter (A) (mm)	Geometric Orifice Area (cm²)	Valve Size (mm)	Standard Model Number	Tissue Annulus Diameter (B) (mm)	Orifice Inner Diameter (A) (mm)	Geometric Orifice Area (cm²)
Standard Intra-annular	19	500FA19	19.5	14.8	1.55	19	500DM19*	19.5	14.8	1.55
	21	500FA21	21.5	16.8	2.02	21	500DM21*	21.5	16.8	2.02
	23	500FA23	23.5	18.8	2.56	23	500DM23*	23.5	18.8	2.56
	25	500FA25	25.5	20.8	3.17	25	500DM25*	25.5	20.8	3.17
	27	500FA27	27.5	22.8	3.84	27	500DM27	27.5	22.8	3.84
	29	500FA29	29.5	24.8	4.59	29	500DM29	29.5	24.8	4.59
	31	500FA31*	31.5	26.8	5.35	31	500DM31*	31.5	26.8	5.35
						33	500DM33	33.5	26.8	5.35



Medtronic Open Pivot™ AP® and AP360® Heart Valves

	AORTIC					MITRAL				
	Valve Size (mm)	AP/AP360 Model Number	Tissue Annulus Diameter (B) (mm)	Orifice Inner Diameter (A) (mm)	Geometric Orifice Area (cm²)	Valve Size (mm)	AP Model Number	Tissue Annulus Diameter (B) (mm)	Orifice Inner Diameter (A) (mm)	Geometric Orifice Area (cm²)
AP/AP360 Supra-annular	16	501DA16 505DA16	16.2	14.8	1.55	16	501DM16*	16.2	14.8	1.55
	18	501DA18 505DA18	18.2	16.8	2.02	18	501DM18*	18.2	16.8	2.02
	20	501DA20 505DA20	20.2	18.8	2.56	20	501DM20*	20.2	18.8	2.56
	22	501DA22 505DA22	22.2	20.8	3.17	22	501DM22	22.2	20.8	3.17
	24	501DA24 505DA24	24.2	22.8	3.84	24	501DM24	24.2	22.8	3.84
	26	501DA26 505DA26	26.2	24.8	4.59	26	501DM26	26.2	24.8	4.59
	28	501DA28* 505DA28*	28.2	26.8	5.35	28	501DM28	28.2	26.8	5.35



*Model not currently available for sale in the United States.

Medtronic Open Pivot™ Sizer Kit

Model Number	Descriptor
576	Open Pivot Sizer Set
580/581	Screw-on Mitral Rotator Set
569	Bendable Handle



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www.medtronic.eu

Europe

Medtronic International Trading Sàrl.
Route du Molliau 31
Case postale
CH-1131 Tolochenaz
www.medtronic.eu
Tel: +41 (0)21 802 70 00
Fax: +41 (0)21 802 79 00

United Kingdom/Ireland

Medtronic Limited
Building 9
Croxley Green Business Park
Hatters Lane
Watford
Herts WD18 8WW
www.medtronic.co.uk
Tel: +44 (0)1923 212213
Fax: +44 (0)1923 241004

Medtronic Open Pivot™ Heart Valve

Indications: The Medtronic Open Pivot™ Heart Valve is indicated for the replacement of diseased, damaged, or malfunctioning native or prosthetic aortic or mitral valves. **Contraindications:** The Medtronic Open Pivot Heart Valve is contraindicated in patients unable to tolerate anticoagulation therapy. Adverse events potentially associated with the use of prosthetic heart valves include: cardiac arrhythmias, death, leaflet entrapment (impingement), endocarditis, hemolysis, anticoagulant-related hemorrhage, transvalvular or perivalvular leak, prosthesis thrombosis, structural deterioration, valve thromboembolism. **CAUTION:** Federal Law restricts this device to sale by or on the order of a physician or properly licensed practitioner. Refer to the Instructions For Use packaged with each valve for a complete listing of warnings and precautions.

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