

Tissue Treatment Comparison

Medtronic Hancock® II vs. St. Jude Medical Biocor®/Epic™ Bioprostheses

Valve	Tissue Treatment	Tissue Treatment Definition	Tissue Treatment Efficacy	Clinical Outcomes for Treated Tissue Valves
Biocor® <i>Available since 1982</i>	None	None	None	None
Epic™ <i>(Biocor valve with Linx™ AC)</i> <i>Available since 1998</i>	Linx™ AC	Involves ethanol treatment of glutaraldehyde fixed valves ¹	"No statistically significant difference was found between the [St. Jude Medical] SJM Epic valve and the standard SJM Biocor valve. . . ." ²	<ul style="list-style-type: none"> "Clinical outcome at 5 years after porcine valve replacement using the Epic xenograft was satisfactory in elderly patients [age ≥70 years]."³ "The clinical effectiveness of the Linx anticalcification treatment remains to be proven during longer term follow up."³
Hancock® II <i>Available since 1982</i>	T6	Sodium dodecyl sulfate removes phospholipids from the xenograft tissue	<ul style="list-style-type: none"> " . . . findings support the clinical results of a delayed occurrence of structural failure of Hancock II bioprostheses and a mitigation of mineralization by the [T6] anti-calcification treatment."⁴ " . . . reported the useful role of T6 in decreasing the extent of calcification in glutaraldehyde-fixed porcine aortic valves. . . ."⁶ "Pretreatment with the antimineralization agent (T6) appears to have been beneficial in delaying/reducing the onset of porcine valve calcification."⁶ " . . . the T6 process inhibits the onset of intrinsic mineralization in glutaraldehyde-fixed xenograft tissues."⁹ 	<ul style="list-style-type: none"> "The Hancock II porcine valve showed excellent 15-year durability. We recommend its use in patients 65 years of age, as well as in younger patients undergoing aortic replacement."⁵ " . . . Hancock II valve is an excellent choice for valve replacement surgery, with low rates of long-term [structural valve disease] SVD and very low rates of other valve-related complications."⁷ " . . . data clearly demonstrated that the Hancock II is an improved version of the first-generation porcine valve with extended durability."⁸ "The results show that the durability, hemodynamics and strength of the valve, and the integrity of the tissue fixation were unaffected by the process."⁹

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"Hancock II really is the gold standard of bioprosthetic heart valves now."¹⁰

– Tirone E. David, MD, 2008



Aortic Valve Replacement (AVR)										
Valve	Paper	n	Mean Age Years	Follow-up Years Mean ± SD (% complete)	Def of Failure	Mid- to Long-term Durability (%)		Overall Survival (%)		
						10 Years	15 Years	10 Years	15 Years	Other
Biocor® <i>Available since 1982</i>	Myken (2000) ¹¹	1029	69	(99.7)	ESVD		76 ± 7 (n<5)		41 ± 3 (n=7)	
	Myken (2005) ¹²	1283	70 ± 11	5.1 (99)	ESVD	~90 (n=182)	73.9 ± 4.1 (n=13)	~55 (n=188)	~30 (n=16)	28.2 ± 3.7 @ 17 yrs
	Bottio (2004) ¹³	257	75 ± 6	median = 5.0 (100)	SVD	95 ± 3.7 @ 8 yrs		37 ± 9		48 ± 5 @ 8 yrs
Epic™ <i>Available since 1998</i>	Lehmann (2007) ³	1168	76 ± 6	1.8 ± 1.3 (100) max = 5.6	SVD	No Data Available		No Data Available		
	IFU (2007) ¹⁴	557	74.4 ± 9.3	1.1 ± 0.7 max = 3.1	N/A					
Hancock® II <i>Available since 1982</i>	Borger (2006) ⁷	1010	67 ± 11	7.4 ± 4.9 yrs (99.9)	ESVD	94 ± 2 for <65* (n=162)	39 ± 9 <65* (n=4) @ 20 yrs	61 ± 2 (n=364)	~40 (n=86)	19 ± 4 @ 20 yrs (n=6)
	Bottio (2003) ⁴	701	not indicated	11.3 ± 1.9 (--)	SVD	99 ± 1 for ≥65* (n=202)	73 ± 16 ≥65* (n=2) @ 20 yrs			
	Rizzoli (2003) ⁵	66	63 ± 9	median = 9.0 (98)	SVD		88.9 ± 6.2 (n=4)	54 (n=27)	28 ± 8 (n=4)	
	Rizzoli (2006) ¹⁵	809	68 ± 8	median = 12.0 (97)	SVD	97.0 ± 0.1 (n=180)	84.7 ± 0.4 (n=26)	59 ± 2.2 (n=181)	39.7 ± 3.5 (n=26)	
	Compendium (2003) ¹⁶	267	median = 67	8.3	ESVD	90 ± 3.2 @ 12 yrs (n=80)	82.9 ± 5.2 @ 14 yrs (n=43)	40.9 ± 3.5 @ 12 yrs (n=80)	32.8 ± 4.1 @ 14 yrs (n=43)	
	David (1995) ¹⁷	536	64 ± 12	4.9 ± 2.8 (98.6)	N/A			63 ± 4 (n=33)		
	David (2001) ¹⁸	670	65 ± 12	6.9 ± 4.2 (99)	SVD	97 ± 1	81 ± 5 (n=18)	61 ± 2	47 ± 3 (n=18)	

Mitral Valve Replacement (MVR)										
Valve	Paper	n	Mean Age Years	Follow-up Years Mean ± SD (% complete)	Def of Failure	Mid- to Long-term Durability (%)		Overall Survival (%)		
						10 Years	15 Years	10 Years	15 Years	Other
Biocor® <i>Available since 1982</i>	Rizzoli (2005) ¹⁹	154	72.3 ± 6	median = 4 (100)	SVD	100		51.1 ± 5.6 (n=8)		
	Pomerantzeff (2006) ²⁰	546	49.2 ± 17.1	4.4 (--)	SVD		51.8 ± 13.8 for <50* (n=1)	~80 (n=31)	45.0 ± 15.8 (n=3)	
	Myken (2000) ¹¹	158	63	(99.7)	ESVD		88.7 ± 5.1 for 51-60* (n=1)			25 ± 11 (n=1)
	Myken (2005) ¹²	172	64 ± 12	5.8 (99)	ESVD	~90 (n=42)	84.0 ± 9.8 for 61-80* (n=1)	~45 (n=42)	35.4 ± 5.0 (n=2)	
Epic™ <i>Available since 1998</i>	Lehmann (2007) ³	101	73.1 ± 7	1.8 ± 1.3 max = 5.6	SVD	No Data Available		No Data Available		
	IFU (2007) ¹⁴	176	72.1 ± 8.9	1.0 ± 0.7 max = 3.1	N/A					
Hancock® II <i>Available since 1982</i>	Borger (2006) ⁷	559	67 ± 11	7.4 ± 4.9 (99.9)	ESVD	82 ± 5 for <65* (n=63)	27 ± 9 <65* (n=2) @ 20 yrs	50 ± 3 (n=124)	~20 (n=27)	6 ± 3 @ 20 yrs (n=3)
	Bottio (2003) ⁴	421	not indicated	11.3 ± 1.9 (--)	SVD	95 ± 2 for ≥65* (n=61)	59 ± 11 ≥65* (n=1) @ 20 yrs			
	Rizzoli (2003) ⁵	114	63 ± 9	median = 9.0 (98)	SVD	86 (n=37)	59.5 ± 3.9 (n=10)	49 (n=43)	37 ± 5.3 (n=18)	
	Rizzoli (2006) ¹⁵	484	66 ± 9	median = 12.0 (97)	SVD	93.2 ± 0.2 (n=115)	70.8 ± 0.5 (n=27)	56.7 ± 2.8 (n=115)	39 ± 3.5 (n=27)	
	Compendium (2003) ¹⁶	102	median = 65	7.2	ESVD	78.4 ± 8.6 @ 12 yrs (n=18)	74.1 ± 13.3 @ 14 yrs (n=8)	28.3 ± 5.6 @ 12 yrs (n=18)	24.4 ± 7.5 @ 14 yrs (n=8)	
	David (1995) ¹⁷	250	64 ± 12	4.9 (98.6)	N/A			55 ± 5 (n=21)		
	David (2001) ¹⁸	310	65 ± 12	7.3 ± 3.8 (99)	SVD	86 ± 3	66 ± 6 (n=9)	52 ± 3	30 ± 5 (n=9)	

Notes: Each set of the 2 Myken, 2 Rizzoli, and the 3 Borger/David papers have the same patient population.
 ~ indicates numbers are estimates from graphs in articles
 * patient age at implant
 If n is absent, it wasn't indicated in the article.

Hancock® II Bioprosthesis

Indications: For patients who require replacement of their native or prosthetic aortic and/or mitral valves.

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: angina, cardiac arrhythmia, cardiac dysrhythmias, death, endocarditis, heart failure, hemolysis, hemolytic anemia, hemorrhage, transvalvular or paravalvular leak, myocardial infarction, nonstructural dysfunction, stroke, structural deterioration, thromboembolism, or valve thrombosis.

For additional information, please refer to the Instructions for Use provided with the product.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.

Hancock is a registered trademark of Medtronic, Inc.

Biocor, Epic, and Linx are trademarks of St. Jude Medical, Inc.

Prospective, randomized trials conducted at the same institution are the highest standard for comparing the clinical performance of different heart valve prostheses; however, few such studies exist. Comparisons of results from prospective, randomized trials conducted at different institutions, or retrospective studies that conform to the published AATS/STS Guidelines for Reporting Morbidity and Mortality After Cardiac Valvular Operations (Edmunds, *Eur J Cardio-Thorac Surg*, 1996) are less robust but can provide useful information, acknowledging their inherent statistical limitations, such as differences in patient characteristics, study objectives, definitions, and statistical reporting. For the exclusive use of physicians.

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UC200804514 EN
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