

**MEDTRONIC HANCOCK® II  
BIOPROSTHESIS  
Instructions for Use**

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# MEDTRONIC HANCOCK® II BIOPROSTHESIS

## Instructions for Use

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

### 1. DEVICE DESCRIPTION

Hancock II Bioprostheses (Model T505, aortic, and Model T510, mitral) consist of porcine aortic valves which have been preserved in stabilized (0.2%) glutaraldehyde with a pressurized aortic root fixation process, and then fitted and secured to flexible acetal homopolymer stents. Hancock II Bioprostheses are treated with a surfactant, sodium dodecyl sulfate ("T6").

The Medtronic Hancock II Bioprostheses are designed for both the aortic position (Model T505) and mitral position (Model T510). They are available in the following implantation diameters:

- Model T505 - 21mm, 23mm, 25mm, 27mm and 29mm
- Model T510 - 25mm, 27mm, 29mm, 31mm and 33mm.

Testing has shown that the presence of this device (with the materials described) in a patient undergoing a MRI (magnetic resonance imaging) procedure using a MR system with a static magnetic field of <1.5 Tesla, will present no substantial or increased risk relative to magnetic field interactions, artifacts and/or heating.

### 2. INDICATIONS

Hancock II Bioprostheses (Models T505 and T510) are indicated for patients who require replacement of their native or prosthetic aortic and mitral valves.

### 3. CONTRAINDICATIONS

None known.

### 4. WARNINGS

FOR SINGLE USE ONLY.

DO NOT RESTERILIZE THE VALVE BY ANY METHOD. Exposure of the bioprosthesis and container to irradiation, steam, ethylene oxide or other chemical sterilants will render the bioprosthesis unfit for use.

WARNING. Accelerated deterioration due to calcific degeneration of bioprostheses may occur in:

- children, adolescents, or young adults;
- patients with abnormal calcium metabolism (e.g., chronic renal failure, hyperparathyroidism).

## 5. PRECAUTIONS

### Precautions Prior to Use

Do not use the Hancock II Bioprosthesis:

- if it has been exposed to freezing or has had prolonged exposure to heat.
- if the tamper evident seal is broken.
- if the glutaraldehyde storage solution does not completely cover the bioprosthesis.

### Precautions During and After Use

- Do not expose to any solution except for the storage solution or sterile saline. Do not expose to antibiotics.
- Do not allow the valve tissue to dry. Maintain tissue moisture with irrigation or immersion in normal saline solution during surgery.
- Passage of a catheter, surgical instrument or transvenous pacing lead through the bioprosthesis may damage the valve.
- A replacement prosthesis should fit the native annulus snugly without over-distension.
- Avoid suture entanglement with the mitral stent posts and verify by examining the ventricular aspect of the implanted bioprosthesis.

## 6. ADVERSE EVENTS

### **Medtronic Long-Term Clinical Study**

A multi-center evaluation was conducted of patients implanted with the Medtronic Hancock II Bioprosthesis, with patient follow-up out to 12 years for some patients. Two hundred sixty-seven (267) patients had isolated aortic valve replacement (AVR) and 102 patients had isolated mitral valve replacement (MVR). Patients were evaluated within 30 days of surgery, and on an annual basis through 1992. Since 1993, patients were evaluated once every other year. Adverse events were captured throughout the postoperative period.

### **Toronto Case Series**

A case series of patients implanted with the Medtronic Hancock II Bioprosthesis was conducted, with patient follow-up out to 14 years for some patients. Seven hundred ten (710) patients had isolated aortic valve replacement (AVR) and 308 patients had isolated mitral valve replacement (MVR). Patients were implanted between September 1982 and December 1994. Patients were evaluated preoperatively, within 30 days of surgery, and at the following follow-up intervals: 1991, 1992-1993, 1994, and 1996. The first occurrence of device-related adverse events was captured (multiple events were not captured) throughout the postoperative period.

## 6.1 Observed Adverse Events

The tables below present early ( $\leq 30$  days for valve-related adverse events,  $\leq 30$  days or during hospitalization for death), linearized and cumulative freedom from adverse event rates. A linearized rate is not calculated for death, structural valve deterioration, nonstructural valve dysfunction, reoperation, and death, since these rates are not constant over time. The denominator used for calculation of the linearized rates was constant in the Medtronic Long-Term Clinical Study (it included only patient-years beyond 30 days), whereas the denominator in the Toronto Case Series varied because patients were censored when the first event of each complication was reported (multiple events were not included).

### Medtronic Long-Term Clinical Study: AVR

The adverse event rates were based on 267 bioprostheses implanted in 267 patients at seven centers. The cumulative follow-up was 1,889 patient-years with a mean follow-up of 7 years (SD=4 years, range=0 to 12 years).

**Table 1: Observed Adverse Event Rates for AVR  
Medtronic Long-Term Clinical Study**

All patients analyzed: N=267 Cumulative follow-up=1,889 patient-years

Adverse Event	Early Events		Late Events <sup>1</sup>		Freedom from Event (%) [95% CI] <sup>2</sup>		
	N	%	N	%/Pt.-Yr.	1 Year (n = 237) <sup>3</sup>	5 Years (n = 180) <sup>3</sup>	10 Years (n = 81) <sup>3</sup>
All Deaths	12	4.5	120	--	91.3 [87.9, 94.7]	72.3 [66.7, 77.9]	49.2 [41.6, 56.8]
Valve-Related or Unexplained	0	0	32	--	98.0 [96.2, 99.8]	92.9 [89.3, 96.5]	82.2 [74.6, 89.8]
<b>Valve-Related Adverse Events</b>							
Thromboembolism <sup>4</sup>	2	0.7	37	2.0	98.0 [96.2, 99.8]	92.9 [89.1, 96.7]	80.7 [72.1, 89.3]
Permanent Neurological Events	2	0.7	19	1.0	99.2 [98.0, 100.0]	96.7 [94.2, 99.2]	90.0 [83.7, 96.3]
Transient Neurological Events	0	0	16	0.9	98.8 [97.4, 100.0]	96.7 [94.2, 99.2]	91.2 [84.7, 97.7]
Primary Valve Thrombosis	0	0	3	0.2	99.6 [98.8, 100.0]	98.7 [97.1, 100.0]	98.7 [96.2, 100.0]
Structural Valve Deterioration	0	0	11	--	100.0 [98.7, 100.0]	100.0 [98.3, 100.0]	94.4 [89.5, 99.3]
Nonstructural Valve Dysfunction <sup>5</sup>	0	0	2	--	99.6 [98.8, 100.0]	99.1 [97.7, 100.0]	99.1 [97.1, 100.0]
Endocarditis	3	1.1	12	0.6	98.0 [96.2, 99.8]	95.8 [92.9, 98.7]	93.0 [87.5, 98.5]
Periprosthetic Leak <sup>6</sup>	0	0	6	0.3	99.6 [98.8, 100.0]	98.5 [96.7, 100.0]	95.6 [91.1, 100.0]
Major Anticoagulant Related Hemorrhage	0	0	5	0.3	100.0 [98.7, 100.0]	99.5 [98.5, 100.0]	98.0 [95.0, 100.0]
Reoperation	0	0	23	--	98.8 [97.4, 100.0]	96.1 [93.3, 98.9]	89.6 [83.3, 95.9]
Explant	0	0	22	--	98.8 [97.4, 100.0]	96.6 [94.0, 99.2]	90.0 [83.8, 96.2]

**Notes:**

- Late event rates were calculated as linearized rates (%/patient-year) based on 1,867.6 patient-years of follow-up (>30 days postoperative).
- Freedom from event rates were calculated using the Kaplan-Meier method. Peto's formula was used for the calculation of the standard errors of these estimates for the confidence intervals for adverse events with at least one occurrence. For adverse events with no occurrences, the lower one-sided confidence limits were calculated as  $(1 - \text{maximum risk}) = (0.05)^{1/N}$ , and N = number of patients remaining at risk.
- Number of patients in study 1, 5, and 10 years after implant
- Two late embolic events were in peripheral arteries.
- Due to pannus
- No events related to endocarditis

### Medtronic Long-Term Clinical Study: MVR

The adverse event rates were based on 102 bioprostheses implanted in 102 patients at seven centers. The cumulative follow-up was 649 patient-years with a mean follow-up of 6 years (SD=4 years, range=0 to 12 years).

**Table 2: Observed Adverse Event Rates for MVR  
Medtronic Long-Term Clinical Study**

All patients analyzed: N=102 Cumulative follow-up=649 patient-years

Adverse Event	Early Events		Late Events <sup>1</sup>		Freedom from Event (%) [95% CI] <sup>2</sup>		
	N	%	N	%/Pt.-Yr.	1 Year (n = 82) <sup>3</sup>	5 Years (n = 65) <sup>3</sup>	10 Years (n = 26) <sup>3</sup>
<b>All Deaths</b>	13	12.7	48	--	81.3 [73.7, 88.9]	67.3 [57.9, 76.7]	38.1 [26.6, 49.6]
Valve-Related or Unexplained	2	2.0	16	--	94.6 [89.8, 99.4]	89.6 [82.6, 96.6]	77.4 [63.3, 91.5]
<b>Valve-Related Adverse Events</b>							
Thromboembolism <sup>4</sup>	3	2.9	20	3.1	94.6 [89.7, 99.5]	89.3 [81.9, 96.7]	73.0 [57.5, 88.5]
Permanent Neurological Events	1	1.0	9	1.4	97.9 [94.8, 100.0]	95.3 [90.2, 100.0]	85.8 [73.1, 98.5]
Transient Neurological Events	2	2.0	8	1.2	97.9 [94.8, 100.0]	95.1 [89.8, 100.0]	91.0 [79.8, 100.0]
Primary Valve Thrombosis	0	0	0	0	100.0 [96.4, 100.0]	100.0 [95.5, 100.0]	100.0 [89.1, 100.0]
Structural Valve Deterioration	0	0	7	--	100.0 [96.4, 100.0]	98.5 [95.6, 100.0]	90.7 [80.1, 100.0]
Nonstructural Valve Dysfunction <sup>5</sup>	0	0	0	--	100.0 [96.4, 100.0]	100.0 [95.5, 100.0]	100.0 [89.1, 100.0]
Endocarditis	0	0	5	0.8	100.0 [96.4, 100.0]	98.8 [96.1, 100.0]	94.6 [86.1, 100.0]
Periprosthetic Leak <sup>6</sup>	1	1.0	1	0.2	99.0 [96.8, 100.0]	97.5 [93.7, 100.0]	97.5 [91.5, 100.0]
Major Anticoagulant Related Hemorrhage	0	0	7	1.1	100.0 [96.4, 100.0]	95.8 [90.9, 100.0]	89.8 [78.6, 100.0]
Reoperation	0	0	8	--	100.0 [96.4, 100.0]	98.5 [95.6, 100.0]	88.5 [77.0, 100.0]
Explant	0	0	8	--	100.0 [96.4, 100.0]	98.5 [95.6, 100.0]	88.5 [77.0, 100.0]

Notes:

- Late event rates were calculated as linearized rates (%/patient-year) based on 641.0 patient-years of follow-up (>30 days postoperative).
- Freedom from event rates were calculated using the Kaplan-Meier method. Peto's formula was used for the calculation of the standard errors of these estimates for the confidence intervals for adverse events with at least one occurrence. For adverse events with no occurrences, the lower one-sided confidence limits were calculated as (1-maximum risk), where (1-maximum risk) =  $(0.05)^{1/N}$ , and N = number of patients remaining at risk.
- Number of patients in study 1, 5, and 10 years after implant
- Three late embolic events were in peripheral arteries.
- Due to pannus
- No events related to endocarditis

### Toronto Case Series: AVR

The adverse event rates were based on 710 bioprostheses implanted in 710 patients at The Toronto Hospital. The cumulative follow-up was 4,064 patient-years with a mean follow-up of 6 years (SD=3 years, range=0 to 14 years).

**Table 3: Observed Adverse Event Rates for AVR  
Toronto Case Series**

All patients analyzed: N=710 Cumulative follow-up=4,064 patient-years

Adverse Event	Early Events		Late Events		Freedom from Event (%) [95% CI] <sup>1</sup>		
	N	%	N	%/Pt.-Yr.	1 Year (n = 648) <sup>2</sup>	5 Years (n = 398) <sup>2</sup>	10 Years (n = 80) <sup>2</sup>
<b>All Deaths</b>	34	4.8	156	--	92.5 [90.5, 94.5]	80.3 [76.8, 83.8]	63.4 [55.0, 71.8]
Valve-Related or Unexplained	--	--	18	--	99.9 [99.7, 100.0]	97.9 [96.5, 99.3]	95.9 [91.6, 100.0]
<b>Valve-Related Adverse Events</b>							
Thromboembolism	6	0.8	48	1.2	98.2 [97.2, 99.2]	94.3 [92.0, 96.6]	86.7 [79.4, 94.0]
Permanent Neurological Events	5	0.7	34	0.9	98.7 [97.8, 99.6]	95.8 [93.8, 97.8]	90.5 [84.3, 96.7]
Transient Neurological Events	1	0.1	14	0.4			
Primary Valve Thrombosis <sup>3</sup>	0	0	0	0	100.0 [99.5, 100.0]	100.0 [99.3, 100.0]	100.0 [96.3, 100.0]
Structural Valve Deterioration <sup>3</sup>	0	0	10	--	100.0 [99.5, 100.0]	99.6 [99.0, 100.0]	95.4 [90.9, 99.9]
Endocarditis	1	0.1	17	0.4	99.4 [98.8, 100.0]	97.8 [96.4, 99.2]	96.2 [92.1, 100.0]
Major Periprosthetic Leak <sup>3</sup>	0	0	3	0.1	99.9 [99.7, 100.0]	99.9 [99.6, 100.0]	99.0 [96.8, 100.0]
Reoperation	0	0	24	--	99.4 [98.8, 100.0]	97.7 [96.2, 99.2]	93.0 [87.6, 98.4]
Explant	0	0	23	--	99.4 [98.8, 100.0]	97.8 [96.4, 99.2]	93.2 [87.9, 98.5]

Notes:

- Freedom from event rates were calculated using the Kaplan-Meier method. Peto's formula was used for the calculation of the standard errors of these estimates for the confidence intervals for adverse events with at least one occurrence. For adverse events with no occurrences, the lower one-sided confidence limits were calculated as (1-maximum risk), where (1-maximum risk) =  $(0.05)^{1/N}$ , and N = number of patients remaining at risk.
- Number of patients in case series 1, 5, and 10 years after implant
- Resulting in reoperation or death

### Toronto Case Series: MVR

The adverse event rates were based on 308 bioprostheses implanted in 308 patients at The Toronto Hospital. The cumulative follow-up was 1720 patient-years with a mean follow-up of 6 years (SD=4 years, range=0 to 14 years).

**Table 4: Observed Adverse Event Rates for MVR  
Toronto Case Series**

All patients analyzed: N=308 Cumulative follow-up=1,720 patient-years

Adverse Event	Early Events		Late Events		Freedom from Event (%) [95% CI] <sup>1</sup>		
	N	%	N	%/Pt.-Yr.	1 Year (n = 269) <sup>2</sup>	5 Years (n = 159) <sup>2</sup>	10 Years (n = 43) <sup>2</sup>
All Deaths	24	7.8	89	--	88.3 [84.7, 91.9]	72.9 [67.0, 78.8]	53.5 [42.6, 64.4]
Valve-Related or Unexplained	--	--	17	--	99.6 [98.8, 100.0]	95.9 [92.9, 98.9]	88.8 [79.9, 97.7]
<b>Valve-Related Adverse Events</b>							
Thromboembolism	1	0.3	17	1.0	99.3 [98.3, 100.0]	94.9 [91.5, 98.3]	90.3 [81.8, 98.8]
Permanent Neurological Events	1	0.3	15	0.9	99.3 [98.3, 100.0]	95.5 [92.3, 98.7]	91.6 [83.6, 99.6]
Transient Neurological Events	0	0	2	0.1	--	--	--
Primary Valve Thrombosis <sup>3</sup>	0	0	1	0.1	100.0 [98.9, 100.0]	100.0 [98.1, 100.0]	99.3 [96.8, 100.0]
Structural Valve Deterioration <sup>3</sup>	0	0	16	--	100.0 [98.9, 100.0]	100.0 [98.1, 100.0]	83.9 [73.8, 94.0]
Endocarditis	0	0	10	0.6	98.9 [97.7, 100.0]	96.1 [93.1, 99.1]	95.3 [89.1, 100.0]
Major Periprosthetic Leak <sup>3</sup>	0	0	2	0.1	100.0 [98.9, 100.0]	99.1 [97.6, 100.0]	99.1 [96.3, 100.0]
Reoperation	0	0	21	--	99.3 [98.3, 100.0]	98.4 [96.5, 100.0]	82.3 [72.0, 92.6]
Explant	0	0	20	--	99.7 [99.0, 100.0]	98.8 [97.1, 100.0]	82.6 [72.3, 92.9]

Notes:

- Freedom from event rates were calculated using the Kaplan-Meier method. Peto's formula was used for the calculation of the standard errors of these estimates for the confidence intervals for adverse events with at least one occurrence. For adverse events with no occurrences, the lower one-sided confidence limits were calculated as (1-maximum risk), where (1-maximum risk) = (0.05)<sup>1/N</sup>, and N = number of patients remaining at risk.
- Number of patients in case series 1, 5, and 10 years after implant
- Resulting in reoperation or death

### 6.2 Potential Adverse Events

Adverse events potentially associated with the use of bioprosthetic heart valves include:

- death
- endocarditis
- hemolysis
- hemorrhage, anticoagulant/antiplatelet-related
- leak, transvalvular or paravalvular
- nonstructural dysfunction (pannus, suture, inappropriate sizing or other)
- structural deterioration (calcification, leaflet tear or other)
- thromboembolism
- valve thrombosis

## 7. CLINICAL STUDIES

The safety endpoints captured in the studies were complications, and effectiveness endpoints were New York Heart Association (NYHA) functional classification and echocardiographic assessments. Also captured were patient demographics. These are presented in the tables below.

**Table 5: Patient Demographics**

<b>Medtronic Long-Term AVR Clinical Study (N = 267)</b>	
Age at implant in years (mean $\pm$ SD, [min., max.])	64 $\pm$ 14, [17, 86]
Gender (% male / % female)	79% / 21%
<b>Etiology</b>	
Stenosis- % of pts. with stenosis alone (% [number in subgroup/N])	58% (154/267)
Insufficiency- % of pts. with insufficiency alone (% [number in subgroup/N])	23% (62/267)
Mixed-% of pts. with stenosis and insufficiency (% [number in subgroup/N])	19% (51/267)
<b>Medtronic Long-Term MVR Clinical Study (N = 102)</b>	
Age at implant in years (mean $\pm$ SD, [min., max.])	63 $\pm$ 11, [26, 85]
Gender (% male / % female)	52% / 48%
<b>Etiology</b>	
Stenosis- % of pts. with stenosis alone (% [number in subgroup/N])	21% (21/102)
Insufficiency- % of pts. with insufficiency alone (% [number in subgroup/N])	65% (66/102)
Mixed-% of pts. with stenosis and insufficiency (% [number in subgroup/N])	15% (15/102)
<b>Toronto Case Series AVR (N = 710)</b>	
Age at implant in years (mean $\pm$ SD, [min., max.])	65 $\pm$ 12, [18, 86]
Gender (% male / % female)	75% / 25%
<b>Etiology</b>	
Stenosis- % of pts. with stenosis alone (% [number in subgroup/N])	46% (325/710)
Insufficiency- % of pts. with insufficiency alone (% [number in subgroup/N])	24% (170/710)
Mixed-% of pts. with stenosis and insufficiency (% [number in subgroup/N])	30% (211/710)
Unknown	<1% (4/710)
<b>Toronto Case Series MVR (N = 308)</b>	
Age at implant in years (mean $\pm$ SD, [min., max.])	65 $\pm$ 11, [22, 86]
Gender (% male / % female)	44% / 57%
<b>Etiology</b>	
Stenosis- % of pts. with stenosis alone (% [number in subgroup/N])	19% (59/308)
Insufficiency- % of pts. with insufficiency alone (% [number in subgroup/N])	61% (188/308)
Mixed-% of pts. with stenosis and insufficiency (% [number in subgroup/N])	19% (59/308)
Unknown	<1% (2/308)

**Table 6: Effectiveness Outcomes, Functional NYHA**

NYHA Class	Preoperative		Latest	
	n/N	%	n/N	%
<b>Medtronic Long-Term AVR Clinical Study (N = 267)</b>				
I	5/267	2%	131/257	51%
II	55/267	21%	50/257	20%
III	169/267	63%	24/257	9%
IV	37/267	14%	9/257	4%
Unknown	1/267	<1%	43/257	17%
<b>Medtronic Long-Term MVR Clinical Study (N = 102)</b>				
I	0/102	0%	33/90	37%
II	11/102	11%	20/90	22%
III	71/102	70%	17/90	19%
IV	18/102	18%	5/90	6%
Unknown	2/102	2%	15/90	17%
<b>Toronto Case Series AVR (N = 710)</b>				
I	19/710	3%	294/489	60%
II	163/710	23%	135/489	28%
III	306/710	43%	58/489	12%
IV	222/710	31%	2/489	<1%
Unknown	0/710	0%	0/489	0%
<b>Toronto Case Series MVR (N = 308)</b>				
I	6/308	2%	70/172	41%
II	22/308	7%	66/172	38%
III	126/308	41%	35/172	20%
IV	154/308	50%	1/172	1%
Unknown	0/308	0%	0/172	0%

Note: Latest assessment in the Medtronic Long-Term Clinical Study ranged from 1984 through 1996. Latest assessment in the Toronto Case Series was in 1996.

**Table 7: Effectiveness Outcomes, Toronto Case Series, Hemodynamics  
Aortic Valve Replacement**

Valvular Regurgitation	% (n/N)
0 (none)	77% (158/205)
1+ (trace/trivial/mild)	15% (31/205)
2+ (mild/moderate)	2% (4/205)
3+ (moderate/severe)	0% (0/205)
4+ (severe)	0% (0/205)
Unknown	6% (12/205)

Mean Pressure Gradient (mmHg)	Number in subgroup/N, mean $\pm$ SD [min., max.]
21 mm	9/13, 12.9 $\pm$ 4.2 [6.0, 19.2]
23 mm	47/53, 13.2 $\pm$ 4.6 [4.8, 26.1]
25 mm	50/60, 11.3 $\pm$ 4.4 [2.1, 26.0]
27 mm	48/57, 11.7 $\pm$ 4.8 [4.0, 24.0]
29 mm	19/22, 10.5 $\pm$ 3.6 [5.3, 19.2]

Note: Studies performed on 205 patients through 5 years postoperatively. Data not available for 32 patients.

Effective Orifice Area (cm <sup>2</sup> )	Number in subgroup/N, mean $\pm$ SD [min., max.]
21 mm	11/13, 1.4 $\pm$ 0.5 [0.8, 2.4]
23 mm	48/53, 1.3 $\pm$ 0.2 [0.9, 1.9]
25 mm	50/60, 1.4 $\pm$ 0.3 [0.9, 2.3]
27 mm	47/57, 1.6 $\pm$ 0.4 [0.9, 2.5]
29 mm	19/22, 1.4 $\pm$ 0.3 [1.0, 2.3]

Note: Studies performed on 205 patients through 5 years postoperatively. Data not available for 30 patients.

**Table 8: Effectiveness Outcomes, Toronto Case Series, Hemodynamics  
Mitral Valve Replacement**

Valvular Regurgitation	% (n/N)
0 (none)	71% (92/130)
1+ (trace/trivial/mild)	22% (29/130)
2+ (mild/moderate)	2% (3/130)
3+ (moderate/severe)	0% (0/130)
4+ (severe)	0% (0/130)
Unknown	5% (6/130)

Mean Pressure Gradient (mmHg)	Number in subgroup/N, mean $\pm$ SD [min., max.]
25 mm	0/2
27 mm	8/25, 4.5 $\pm$ 2.5 [2.3, 10.0]
29 mm	8/33, 4.1 $\pm$ 1.6 [2.0, 6.0]
31 mm	8/55, 3.8 $\pm$ 1.8 [2.0, 6.0]
33 mm	1/15, 3.0 [3.0, 3.0]

Note: Studies performed on 130 patients through 5 years postoperatively. Data not available on 105 patients.

Effective Orifice Area (cm <sup>2</sup> )	Number in subgroup/N, mean $\pm$ SD [min., max.]
25 mm	1/2, 4.5 [4.5, 4.5]
27 mm	20/25, 2.5 $\pm$ 0.8 [1.2, 4.6]
29 mm	33/33, 2.7 $\pm$ 0.6 [1.4, 4.2]
31 mm	49/55, 2.6 $\pm$ 0.7 [1.2, 5.0]
33 mm	15/15, 3.0 $\pm$ 0.9 [1.0, 4.4]

Note: Studies performed on 130 patients through 5 years postoperatively. Data not available on 12 patients.

## **8. INDIVIDUALIZATION OF TREATMENT**

Anticoagulant and/or Antiplatelet Therapy -- Long-term anticoagulant and/or antiplatelet therapy should be considered for patients with a dilated left atrium, a history of thrombotic events, or with atrial fibrillation or flutter.

### **8.1 Specific Patient Populations**

The safety and effectiveness of the Medtronic Hancock II Bioprosthesis has not been established for the following specific populations because it has not been studied in these populations:

- patients who are pregnant;
- nursing mothers;
- patients with abnormal calcium metabolism (e.g., chronic renal failure, hyperparathyroidism);
- patients with aneurysmal aortic degenerative conditions (e.g., cystic medial necrosis, Marfan's Syndrome);
- children, adolescents, or young adults.

## **9. PATIENT COUNSELING INFORMATION**

In some conditions, patients may require anticoagulation and/or antiplatelet therapy for an indefinite period.

Patients with bioprostheses are at risk for bacteremia (e.g., undergoing dental procedures) and should be advised about prophylactic antibiotic therapy.

## **10. HOW SUPPLIED**

### **10.1 Packaging**

The Medtronic Hancock II Bioprosthesis is chemically sterilized and is supplied STERILE in a buffered 0.2% glutaraldehyde storage solution. Sterility is compromised if the package is opened or damaged. The outside of the container is NOT sterile.

### **10.2 Storage**

The Medtronic Hancock II Bioprosthesis must be stored between 5° and 25°C (41° and 77°F). Refrigeration is not required and freezing may damage the bioprosthesis. Room temperature storage (up to 25°C or 77°F) is satisfactory, provided the bioprosthesis is not exposed to sunlight or other ultraviolet light sources or placed where significant temperature fluctuations may occur.

The storage life of the Medtronic Hancock II Bioprosthesis is three (3) years from date of sterilization. Appropriate inventory control should be maintained so that bioprostheses with earlier expiration dates are preferentially implanted and expiration is avoided.

## **11. DIRECTIONS FOR USE**

### **11.1 Physician Training**

No special training is required to implant Medtronic Hancock II Bioprostheses. The techniques for implanting these bioprostheses are similar to those used for any stented bioprosthesis.

## 11.2 Device Features

Hancock II stents are constructed from acetal homopolymer. The stent has a slightly lower profile (approximately 2mm) for all bioprosthesis sizes as compared to the Hancock Standard Bioprosthesis.

The inflow aspects of the aortic and mitral bioprostheses approximate the natural anatomy of the respective annuli. The aortic bioprosthesis stent and sewing ring are scalloped, whereas the mitral bioprosthesis stent and sewing ring are flat.

The stents are covered with polyester fabric. The mitral bioprosthesis sewing ring contains polyester felt. The aortic bioprosthesis sewing ring is scalloped to enable implantation either within the annulus or within the supra-annular position. The aortic sewing ring is mounted flush with the inflow edge of the stent. If the supra-annular position is preferred, the entire bioprosthesis can be seated supra-annularly allowing the use of a larger aortic bioprosthesis in the patient with a small aortic annulus.

Disposable acetal polymer holders are sutured to both aortic and mitral bioprostheses. The mitral bioprosthesis holder incorporates a ratchet mechanism which, after screwing the bioprosthesis holder onto the handle, is actuated by further rotation. This draws the stent posts inward, facilitating passage through the annulus.

The disposable holders are designed to fit the reusable Medtronic Handle (Model 0791). The handle is equipped with a knurled locknut to allow the bioprosthesis to be oriented and secured in a given position with respect to the handle. The handle is also used with the Hancock II valve obturators for measuring the annulus.

Both the aortic and mitral bioprostheses stents are fitted with annular rings and stent post markers for radiographic visualization. The stent post markers are placed close to the apex of each stent post to enable relationship to the aortic and ventricular walls to be visualized.

## 11.3 Handling and Preparation Instructions

Proper bioprosthesis size selection is an important part of heart valve replacement. Size of the Medtronic Hancock II Bioprosthesis is determined using an aortic or mitral obturator (Models 7505 and 7510 respectively). For further information refer to the Medtronic Hancock II Obturator Instructions for Use.

Within the sterile operative field, prepare three rinse basins, each containing 500 ml of sterile normal saline solution.

The exterior of the bioprosthesis container and lid are nonsterile. Examine the lid seal to verify that the bioprosthesis container has not been damaged or previously opened. Turn the lid counter clockwise to open the container (Figure 1). The bioprosthesis, retainer and all internal packaging components within the container are sterile. With the thumb and index finger of a sterile gloved hand, grasp the retainer by the middle bar and slowly lift it out of the container allowing for drainage of the glutaraldehyde storage solution (Figure 2).

Carefully release the identification tag from the notches at the base of the retainer (Figure 3).

Keep the retainer upright. Remove its cap by turning it counterclockwise using the thumb and index finger (Figure 4). The inflow aspect of the bioprosthesis will be visible.

Hold the identification tag suture between the second and third fingers of the free hand to assure that the tag does not interfere with bioprosthesis removal. While holding the suture, tip the retainer upside down over the first rinse basin. The bioprosthesis in its holder will fall into the free hand (Figure 5). The bioprosthesis will have a retainer collar around it. If the bioprosthesis does not fall, gently tap the retainer against the palm of the hand.

Holding the bioprosthesis over the first rinse basin, with the three stent posts facing upward, position the identification tag suture between the collar and the bioprosthesis sewing ring.

Using both hands, grasp the collar on each side of the opening. Open the collar by moving the sides away from each other allowing the bioprosthesis to slide into the rinse basin (Figure 6).

If the bioprosthesis does not fall freely from the collar, the index finger may be used to guide it out. At no time should the tissue portion of the bioprosthesis be touched.

Retrieve the bioprosthesis from the basin. Remove the identification tag from the bioprosthesis and record the serial number in the patient's record.

### **RINSE PROCEDURE**

Continually agitate the bioprosthesis in the holder for a minimum of two minutes in each of the three previously prepared rinse basins. In each basin, gently squeeze the sewing cushion to remove the residual glutaraldehyde. The bioprosthesis should remain in the third rinse basin until ready for implantation.

If preferred, the bioprosthesis may be rinsed in the three basins after the handle is attached to the bioprosthesis holder.

Screw the sterile locknut completely onto the Medtronic Handle (Model 0791), then screw the handle into the bioprosthesis holder while lightly grasping the sewing ring of the bioprosthesis. Tighten the locknut against the holder (Figures 7 and 8).

**Caution:** Do not overtighten the handle.

#### 11.4 Device Implantation

**Caution:** Do not use if the valve has been damaged.

**Caution:** Extreme care must be taken to prevent damage to the delicate valve tissue. Do not handle the tissue portion of the bioprosthesis with instruments. Even the most minor perforation may enlarge in time to produce significant impairment of valve function. Should a bioprosthesis be damaged during insertion, do not attempt repair.

**Caution:** Ensure proper orientation of the valve.

**Caution:** Do not use cutting needles, as they may cause structural damage to the fabric of the bioprosthesis.

**Caution:** Passage of a catheter through any bioprosthesis may damage the delicate valve tissue and is, therefore, not recommended.

#### Aortic Bioprosthesis

**Caution:** Orient the bioprosthesis to avoid obstruction of the coronary ostia.

To change angular orientation, loosen the locknut, unscrew the holder an appropriate amount, and retighten the locknut.

During implantation, the bioprosthesis should be periodically irrigated with sterile normal saline to prevent drying of the delicate valve tissue. Following placement of the sutures in the sewing ring, and positioning the bioprosthesis in the annulus, gently remove the holder by cutting all three sutures with scissors or scalpel in the protected area (Figure 9).

After cutting the three sutures, hold the bioprosthesis in place and gently pull away the handle. The holder and retaining sutures will pull free from the bioprosthesis. Examine the sewing ring and holder to ensure that no suture remnants remain with the bioprosthesis. The holder should then be unscrewed from the handle and discarded.

## **Mitral Bioprosthesis**

Actuate the ratchet mechanism of the holder by lightly grasping the sewing ring of the bioprosthesis and rotating the bioprosthesis clockwise. The stent posts are thus deflected to facilitate insertion of the bioprosthesis into the patient's annulus. The posts should not be deflected more than surgically necessary.

**Caution:** Use of the mitral bioprosthesis in patients with a small left ventricle may result in perforation of the ventricular wall by the stent posts.

**Caution:** Orient the mitral bioprosthesis to position the green suture marker on the atrial aspect of the sewing ring at the posterior mitral commissure. This will minimize potential for obstruction to aortic outflow by orientation.

To change angular orientation, loosen the locknut, unscrew the holder an appropriate amount, and retighten the locknut.

During implantation, periodically irrigate the bioprosthesis with sterile normal saline to prevent drying delicate valve tissue. Following placement of the sutures, the bioprosthesis should be lowered into the annulus, taking care to prevent suture entanglement. Maintaining tension on the sutures at this point is helpful.

Following placement of the bioprosthesis in the annulus, the holder should be removed by cutting the three retaining sutures with scissors or scalpel (Figure 10).

After cutting the three sutures, hold the bioprosthesis in place while gently pulling away the handle with the holder. Examine the sewing ring and holder to ensure that no suture remnants remain with the bioprosthesis. The holder should then be unscrewed from the handle and discarded.

### **11.5 Accessories**

Use only Medtronic Hancock II aortic or mitral bioprosthesis obturators (Models 7505 and 7510, respectively) and the Medtronic Handle (Model 0791) to determine the appropriate Medtronic Hancock II Bioprosthesis size. Valve obturators are provided in aortic and mitral configurations for each size bioprosthesis.

**Caution:** Do not use other manufacturer's valve obturators, or obturators for another Medtronic prosthesis to size the Medtronic Hancock II Bioprostheses.

### **11.6 Return of Explanted Bioprostheses**

Medtronic, Inc. is interested in obtaining recovered Hancock II Bioprostheses. Specific pathological studies of the explant will be determined under the direction of a consulting pathologist. A written report summarizing the findings will be returned to the physician. Product return kits, including an explant information form, are available by contacting Medtronic, Inc. distribution centers and your Medtronic Sales Representative. It is

important that the explant form be completely filled out. If a kit is not available, place the explanted bioprosthesis in a container of glutaraldehyde or 10% buffered formalin immediately after excision. For further instructions on the return of an explanted device, contact your Medtronic Sales Representative.

## **12. PATIENT INFORMATION**

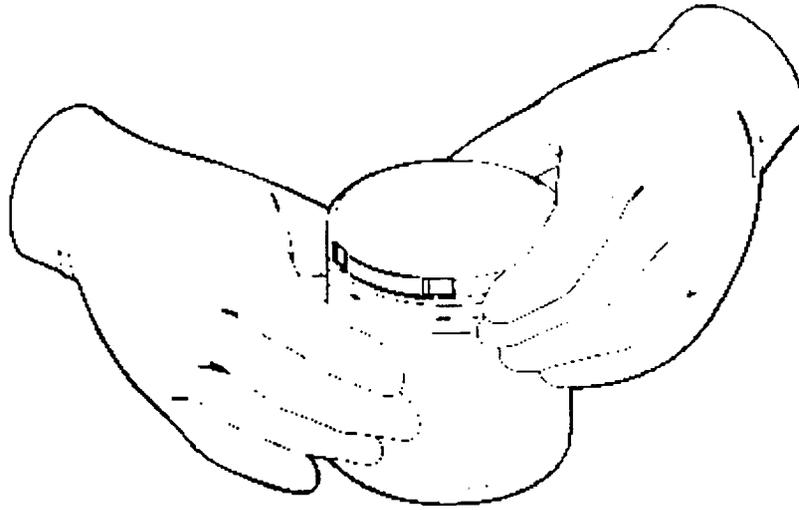
### **12.1 Registration Information**

A patient registration form is included in each device package. After implantation, please complete all requested information. The serial number may be found on the package and on the identification tag attached to the bioprosthesis. Return the original form to the Medtronic address indicated on the form and provide the temporary identification card to the patient prior to discharge. For multiple implantations, use a separate form for each bioprosthesis.

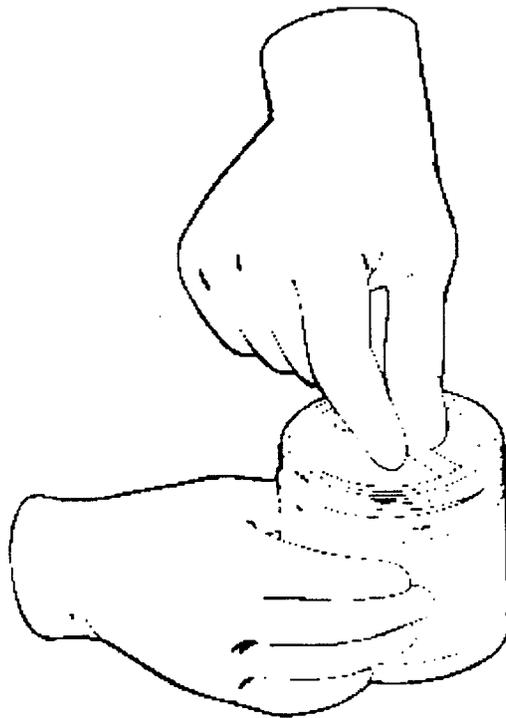
An Implanted Device Identification Card is provided to the patient. The card contains the name and telephone number of the patient's physician, as well as, information that medical personnel would require in the event of an emergency.

### **12.2 Patient Manual**

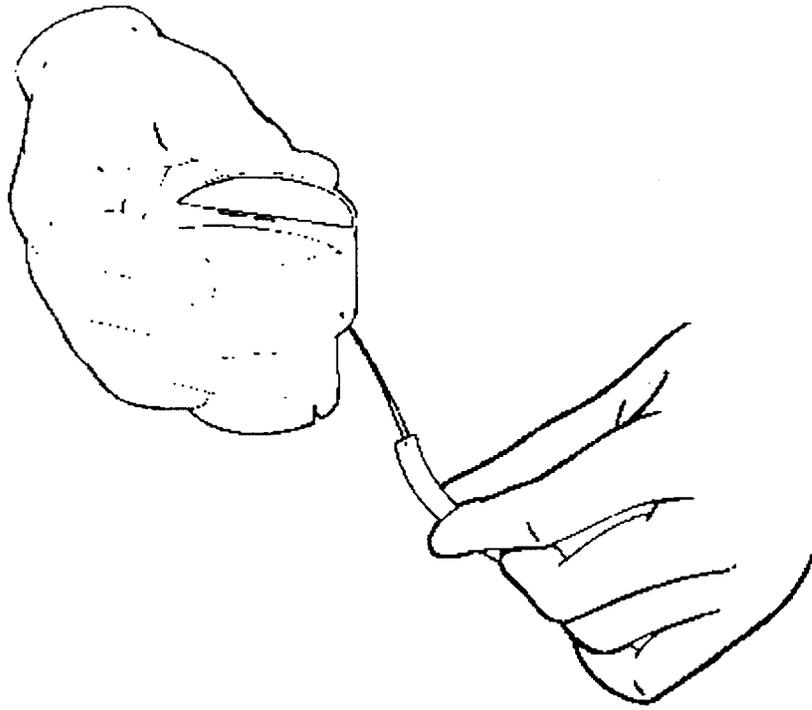
Medtronic has prepared a Patient Information Pamphlet which the physician should provide to the patient prior to discharge. Copies of these pamphlets may be obtained from the Medtronic Sales Representative.



**Figure 1. Opening Valve Jar**



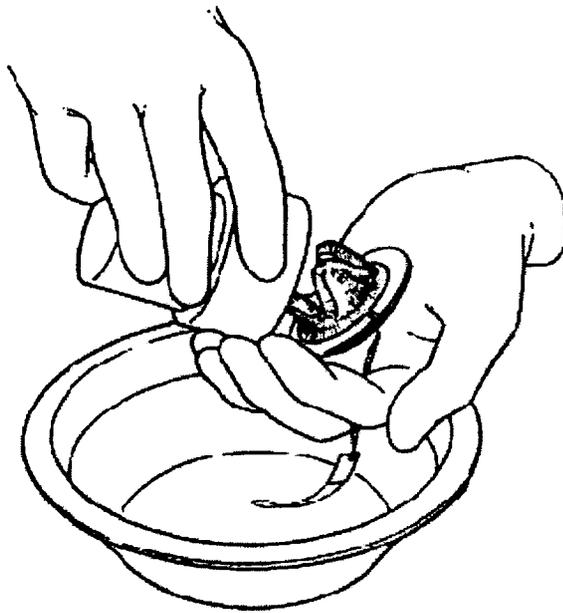
**Figure 2. Removal of Retainer from Jar**



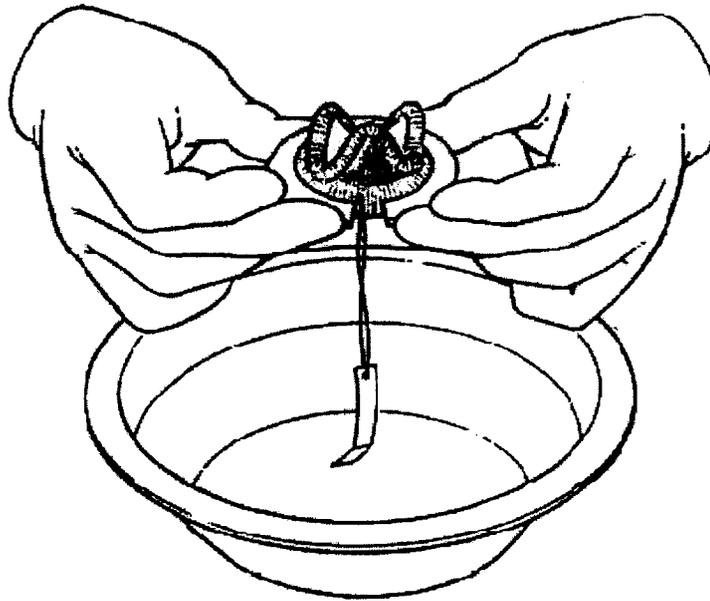
**Figure 3. Release of Identification Tag (serial number)**



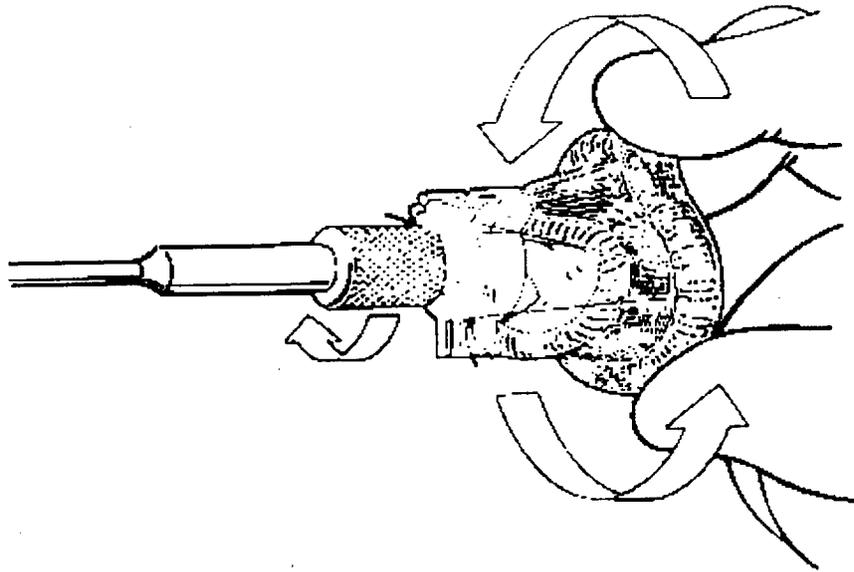
**Figure 4. Retainer Cap Removal**



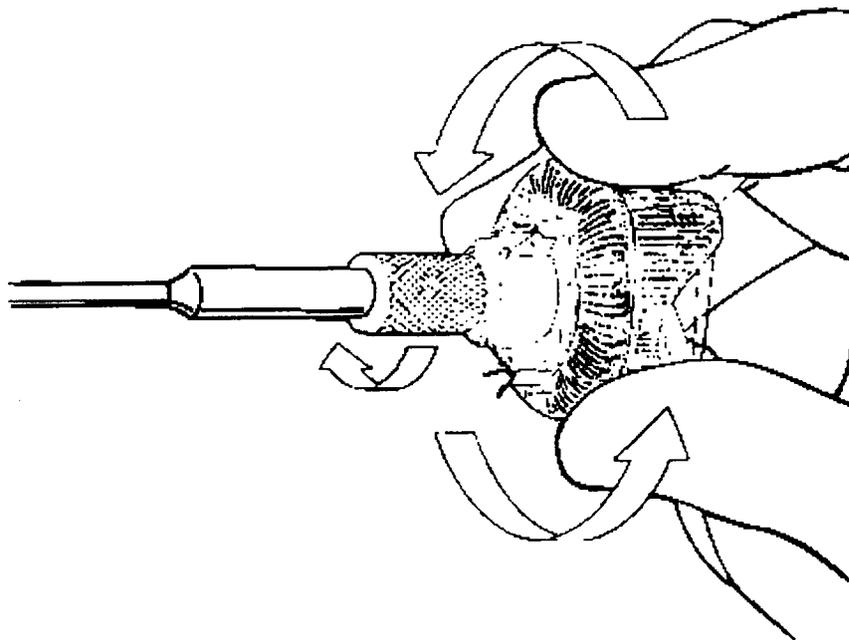
**Figure 5. Valve Removal from Retainer**



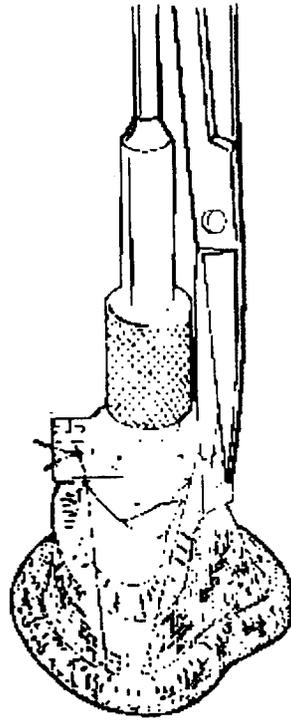
**Figure 6. Retainer Collar Removal**



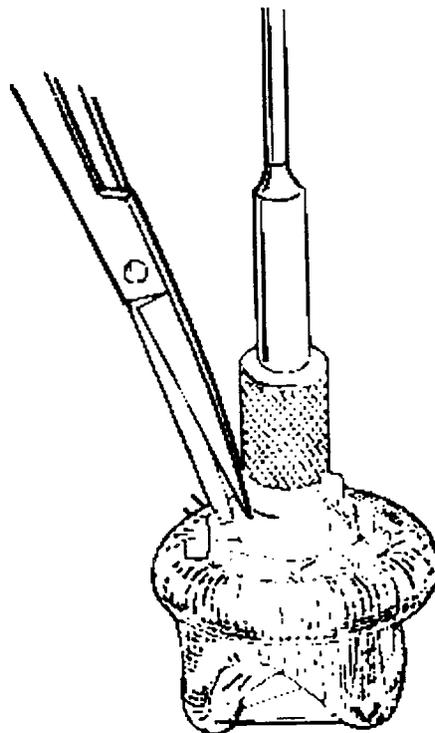
**Figure 7.** Screwing valve holder onto handle and tightening locknut (Aortic)



**Figure 8.** Screwing valve holder onto handle and tightening locknut (Mitral)



**Figure 9. Removal of Aortic Holder**



**Figure 10. Removal of Mitral Holder**