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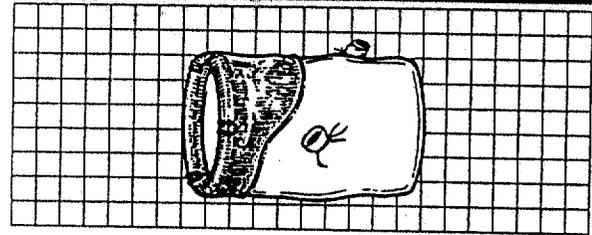
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FREESTYLE®



■ **Instructions for Use**

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MEDTRONIC FREESTYLE®
AORTIC ROOT BIOPROSTHESIS
Instructions for Use

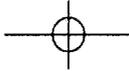


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MEDTRONIC FREESTYLE® AORTIC ROOT BIOPROSTHESIS Instructions for Use

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

1. DEVICE DESCRIPTION

The Medtronic FREESTYLE Aortic Root Bioprosthesis (Medtronic FREESTYLE Bioprosthesis), Model 995, is comprised of a porcine aortic root preserved in buffered 0.2% glutaraldehyde with a cloth covering added to strengthen the proximal (inflow) suture line and to cover any exposed porcine myocardium. The Medtronic FREESTYLE Bioprosthesis is treated according to the AOA™ process, which uses alpha-amino oleic acid, a compound derived from oleic acid, a naturally occurring long-chain fatty acid. The design of the Medtronic FREESTYLE Bioprosthesis allows the physician to trim the prosthesis for replacement using the subcoronary, full-root or root-inclusion technique. It is available in 19mm, 21mm, 23mm, 25mm and 27mm diameters.

2. INDICATIONS

The Medtronic FREESTYLE Bioprosthesis is indicated for the replacement of malfunctioning native or prosthetic aortic valves with the option of aortic root replacement.

*No clinical data are available which evaluate the long-term impact of the AOA treatment in patients.

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3. CONTRAINDICATIONS

No contraindications for use of this device are 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 altered calcium metabolism (e.g., chronic renal failure, hyperparathyroidism).

5. PRECAUTIONS

Implanting physicians must be familiar with the techniques for implanting an unstented bioprosthesis. These techniques are similar to those required for allograft implantation.

In vitro testing of the Medtronic FREESTYLE Bioprosthesis has only been performed in less compliant simulated aorta comparable to the aorta of middle aged or older patients. Data from clinical or *in vitro* testing are not available from more compliant simulated aorta comparable to the aorta of a younger patient.

Limited implant experience is available for the 19mm bioprosthesis implanted with the root-inclusion technique (none), and with the full-root technique (nine patients); and for the 21mm bioprosthesis implanted with the root-inclusion technique (four patients) (see section 7, Clinical Studies).

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Precautions Prior to Use

Do not use the Medtronic FREESTYLE Bioprosthesis:

- if the tamper evident seal is broken;
- if the glutaraldehyde storage solution does not completely cover the bioprosthesis;
- if the bioprosthesis has been exposed to freezing or has had prolonged exposure to heat as indicated by the temperature indicators provided in the packaging;
- if the bioprosthesis is damaged.

Precautions During Use

- Do not expose the bioprosthesis to solutions other than the storage solution in which it was shipped, the sterile isotonic saline solution used during the rinsing procedure, or the sterile isotonic saline used to irrigate the bioprosthesis.
- Do not allow the tissue of the bioprosthesis to dry. Continuous submersion or irrigation is required (see section 11.3 Handling and Preparation Instructions).
- Do not add antibiotics to either the storage or the rinse solution. Do not apply antibiotics to the bioprosthesis.
- Do not lacerate the leaflet tissue. If a valve is damaged, the valve must be explanted and replaced.
- Do not evert the valve. Eversion will damage valve tissue.
- Passage of a catheter through any bioprosthesis may damage the valve and is, therefore, not recommended.
- Trim suture ends close to the knot to prevent abrasion of leaflet tissue.

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6. ADVERSE EVENTS

A prospective non-randomized multicenter international study evaluated the Medtronic FREESTYLE Bioprosthesis with patient follow-up out to three years. A total of 882 patients received the bioprosthesis. Patients were monitored throughout the entire postoperative period for possible adverse events. The cumulative follow-up was 1246 patient-years with a mean follow-up of 17 months (SD = 12 months, range = 0 to 42 months).

6.1 Observed Adverse Events Subcoronary Technique

A total of 640 Medtronic FREESTYLE Bioprostheses were implanted with the subcoronary technique in 640 patients at 15 centers. Nine of the 640 patients were excluded from the data summary of adverse events for the following reasons: five patients had their bioprosthesis removed and replaced with another prosthesis during the initial surgery due to difficulty sizing a small aortic root, high mean gradient, or patient prosthesis mismatch; and four patients had either a pre-existing or concomitant implant of a mitral valve prosthesis.

The adverse event rates were based on 631 bioprostheses implanted in 631 patients. The cumulative follow-up was 913 patient-years with a mean follow-up of 17 months (SD = 11 months, range = 0 to 42 months).

Table 6.1: Observed Adverse Events for the Subcoronary Technique
All patients analyzed, N=631,
Cumulative follow-up = 913 patient-years

	Early Events ¹		Late Events	
	N	% of Patients	N	% / Patient-Year ²
All Deaths	31	4.9%	31	3.6%
Bioprosthesis-Related or Unexplained	4	0.6%	9	1.0%
Study Bioprosthesis-Related AEs				
Thromboembolism ¹	14	2.2%	13	1.5%
Permanent Neurological Event	11	1.7%	6	0.7%
Transient Neurological Event	3	0.5%	6	0.7%
Bioprosthetic Thrombosis	0	0.0%	1	0.1%
Structural Deterioration ¹	0	0.0%	0	0.0%
Nonstructural Dysfunction ¹	0	0.0%	0	0.0%
Major Antithromboembolic-Related Hemorrhage	10	1.6%	7	0.8%
Primary Paravalvular Leak	3	0.5%	8	0.9%
Endocarditis	2	0.3%	8	0.9%
Primary Hemolysis ¹	0	0.0%	0	0.0%
Reoperation	0	0.0%	7	0.8%
Explant	0	0.0%	6	0.7%

	Actuarial Freedom by Kaplan-Meier (%)	
	1 Year (95% CI)	3 Years (95% CI)
All Deaths	91.6% [89.0% - 94.2%]	85.9% [77.5% - 94.3%]
Bioprosthesis-Related or Unexplained	97.9% [96.5% - 99.3%]	97.5% [93.5% - 100.0%]
Study Bioprosthesis-Related AEs		
Thromboembolism ¹	95.6% [93.6% - 97.6%]	94.6% [88.8% - 100.0%]
Permanent Neurological Event	97.3% [95.8% - 98.8%]	96.6% [91.9% - 100.0%]
Transient Neurological Event	98.5% [97.3% - 99.7%]	98.2% [94.7% - 100.0%]
Bioprosthetic Thrombosis	99.8% [99.4% - 100.0%]	99.8% [98.6% - 100.0%]
Structural Deterioration ²	100.0% [99.1% - 100.0%]	100.0% [93.7% - 100.0%]
Nonstructural Dysfunction ³	100.0% [99.1% - 100.0%]	100.0% [93.7% - 100.0%]
Major Antithromboembolic-Related Hemorrhage	97.0% [95.4% - 98.6%]	97.0% [92.6% - 100.0%]
Primary Paravalvular Leak	98.6% [97.5% - 99.7%]	97.6% [93.6% - 100.0%]
Endocarditis	98.5% [97.3% - 99.7%]	97.9% [94.2% - 100.0%]
Primary Hemolysis ⁴	100.0% [99.1% - 100.0%]	100.0% [93.7% - 100.0%]
Reoperation	98.9% [97.9% - 99.9%]	98.6% [95.6% - 100.0%]
Explant	99.0% [98.0% - 100.0%]	98.7% [95.8% - 100.0%]

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Notes:

AEs = Adverse Events

1. Hospital or 30 day event for death or 30 day event for adverse events.

2. Calculations were based on 864 late patient-years.

3. One late event was a peripheral arterial embolus.

4. The number of patients remaining at risk at one year (N=415) and three years (N=57) was used for N in the calculations of the lower confidence limits for the actuarial estimates. The calculation methods are described in the following note.

Note: Adverse event rates were calculated as the percentage of patients for early events. For late adverse events, the linearized rates (%/patient-year) were calculated. For time to first event (early or late), actuarial rates using the Kaplan-Meier method and confidence intervals were calculated. For adverse events with no occurrences, the lower two-sided 95% confidence limits for the Kaplan-Meier estimates were calculated as (1-maximum risk), where (1-maximum risk) is equal to $(0.025)^{1/N}$. If there was no censoring, N would be the total sample size. Since there was censoring, the number of patients remaining at risk at one and three years was used for N. Using the number of patients remaining at risk ignores the experience of all the patients who were censored before the relevant time points and therefore, overestimates the maximum risk.

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Full-Root Technique

A total of 159 Medtronic FREESTYLE Bioprostheses were implanted with the full-root technique in 159 patients at 14 centers. Two of the 159 patients were excluded from the data summary of adverse events for the following reasons: two patients had either a pre-existing or concomitant implant of a mitral valve prosthesis.

The adverse event rates were based on 157 bioprostheses implanted in 157 patients. The cumulative follow-up was 189 patient-years with a mean follow-up of 14 months (SD = 13 months, range = 0 to 39 months).

Table 6.2: Observed Adverse Events for the Full-Root Technique
 All patients analyzed, N=157,
 Cumulative follow-up = 189 patient-years

	Early Events ¹		Late Events	
	N	% of Patients	N	% / Patient-Year ²
All Deaths	22	14.0%	8	4.5%
Bioprosthesis-Related or Unexplained	1	0.6%	4	2.2%
Study Bioprosthesis-Related AEs				
Thromboembolism ³	5	3.2%	6	3.4%
Permanent				
Neurological Event	2	1.3%	3	1.7%
Transient Neurological Event	2	1.3%	3	1.7%
Bioprosthetic Thrombosis ⁴	0	0.0%	0	0.0%
Structural Deterioration ⁵	0	0.0%	0	0.0%
Nonstructural Dysfunction ⁶	0	0.0%	0	0.0%
Major Antithromboembolic-Related Hemorrhage	2	1.3%	1	0.6%
Primary Paravalvular Leak	1	0.6%	0	0.0%
Endocarditis ⁷	0	0.0%	0	0.0%
Primary Hemolysis ⁸	0	0.0%	0	0.0%
Reoperation ⁹	0	0.0%	0	0.0%
Explant ¹⁰	0	0.0%	0	0.0%

	Actuarial Freedom by Kaplan-Meier (%)	
	1 Year (95% CI)	3 Years (95% CI)
All Deaths	79.8% [72.0% - 87.6%]	78.5% [62.5% - 94.5%]
Bioprosthesis-Related or Unexplained	96.3% [92.3% - 100.0%]	94.7% [85.1% - 100.0%]
Study Bioprosthesis-Related AEs		
Thromboembolism ¹	93.3% [87.9% - 98.7%]	90.1% [76.2% - 100.0%]
Permanent Neurological Event	96.6% [92.7% - 100.0%]	95.0% [85.4% - 100.0%]
Transient Neurological Event	96.3% [92.2% - 100.0%]	94.7% [84.3% - 100.0%]
Bioprosthetic Thrombosis ²	100.0% [95.5% - 100.0%]	100.0% [83.2% - 100.0%]
Structural Deterioration ³	100.0% [95.5% - 100.0%]	100.0% [83.2% - 100.0%]
Nonstructural Dysfunction ⁴	100.0% [95.5% - 100.0%]	100.0% [83.2% - 100.0%]
Major Antithromboembolic-Related Hemorrhage	97.7% [94.4% - 100.0%]	97.7% [91.0% - 100.0%]
Primary Paravalvular Leak	99.2% [97.3% - 100.0%]	99.2% [95.3% - 100.0%]
Endocarditis ⁵	100.0% [95.5% - 100.0%]	100.0% [83.2% - 100.0%]
Primary Hemolysis ⁶	100.0% [95.5% - 100.0%]	100.0% [83.2% - 100.0%]
Reoperation ⁷	100.0% [95.5% - 100.0%]	100.0% [83.2% - 100.0%]
Explant ⁸	100.0% [95.5% - 100.0%]	100.0% [83.2% - 100.0%]

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Notes:

AEs = Adverse Events

1. Hospital or 30 day event for death or 30 day event for adverse events.

2. Calculations were based on 179 late patient-years.

3. One early event was a peripheral arterial embolus.

4. The number of patients remaining at risk at one year (N=81) and three years (N=20) was used for N in the calculations of the lower confidence limits for the actuarial estimates. The calculation methods are described in the note following Table 6.1.

Root-Inclusion Technique

A total of 83 Medtronic FREESTYLE Bioprostheses were implanted with the root-inclusion technique in 83 patients at 14 centers. Three of the 83 patients were excluded from the data summary of adverse events for the following reasons: three patients had their bioprosthesis removed and replaced with another prosthesis during the initial surgery due to a leaflet tear during suturing, difficulty seating and orienting the coronaries, or a paravalvular leak.

The adverse event rates were based on 80 bioprostheses implanted in 80 patients. The cumulative follow-up was 139 patient-years with a mean follow-up of 21 months (SD = 13 months, range = 0 to 39 months).

Table 6.3: Observed Adverse Events for the Root-Inclusion Technique

All patients analyzed, N=80,

Cumulative follow-up = 139 patient-years

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	Early Events ¹		Late Events	
	N	% of Patients	N	% / Patient-Year ¹
All Deaths	4	5.0%	5	3.8%
Bioprosthesis-Related or Unexplained	3	3.8%	3	2.3%
Study Bioprosthesis-Related AEs				
Thromboembolism	3	3.8%	7	5.3%
Permanent Neurological Event	0	0.0%	2	1.5%
Transient Neurological Event	3	3.8%	5	3.8%
Bioprosthetic Thrombosis ²	0	0.0%	0	0.0%
Structural Deterioration ³	0	0.0%	0	0.0%
Nonstructural Dysfunction ⁴	0	0.0%	0	0.0%
Major Antithromboembolic-Related Hemorrhage	2	2.5%	0	0.0%
Primary Paravalvular Leak	2	2.5%	0	0.0%
Endocarditis	1	1.3%	1	0.8%
Primary Hemolysis ⁵	0	0.0%	0	0.0%
Reoperation	2	2.5%	2	1.5%
Explant	2	2.5%	2	1.5%

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	Actuarial Freedom by Kaplan-Meier (%)	
	1 Year (95% CI)	3 Years (95% CI)
All Deaths	88.8% [80.9% - 96.7%]	87.0% [72.5% - 100.0%]
Bioprosthesis-Related or Unexplained	91.5% [84.4% - 98.6%]	91.5% [79.2% - 100.0%]
Study Bioprosthesis-Related AEs		
Thromboembolism	91.3% [83.8% - 98.8%]	87.2% [70.2% - 100.0%]
Permanent Neurological Event	98.3% [95.0% - 100.0%]	96.3% [87.3% - 100.0%]
Transient Neurological Event	93.0% [86.1% - 99.9%]	87.6% [71.5% - 100.0%]
Bioprosthetic Thrombosis ²	100.0% [93.5% - 100.0%]	100.0% [81.5% - 100.0%]
Structural Deterioration ³	100.0% [93.5% - 100.0%]	100.0% [81.5% - 100.0%]
Nonstructural Dysfunction ⁴	100.0% [93.5% - 100.0%]	100.0% [81.5% - 100.0%]
Major Antithromboembolic-Related Hemorrhage	97.4% [93.2% - 100.0%]	97.4% [90.1% - 100.0%]
Primary Paravalvular Leak	97.4% [93.2% - 100.0%]	97.4% [90.1% - 100.0%]
Endocarditis	96.9% [92.4% - 100.0%]	96.9% [89.0% - 100.0%]
Primary Hemolysis ⁵	100.0% [93.5% - 100.0%]	100.0% [81.5% - 100.0%]
Reoperation	94.4% [88.5% - 100.0%]	94.4% [84.1% - 100.0%]
Explant	94.4% [88.5% - 100.0%]	94.4% [84.1% - 100.0%]

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Notes:

AEs = Adverse Events

1. Hospital or 30 day event for death or 30 day event for adverse events.
2. Calculations were based on 133 late patient-years.
3. The number of patients remaining at risk at one year (N=55) and three years (N=18) was used for N in the calculations of the lower confidence limits for the actuarial estimates. The calculation methods are described in the note following Table 6.1.

6.2 Potential Adverse Events

Adverse events potentially associated with the use of bioprosthetic heart valves (in alphabetical order) include:

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

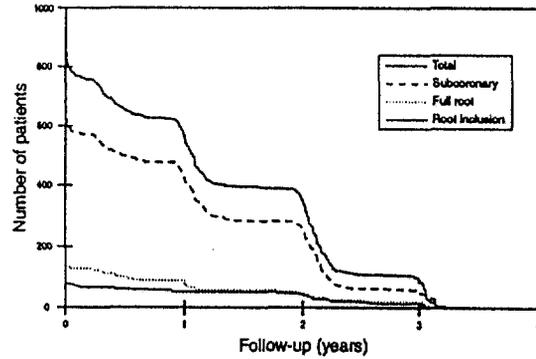
7. CLINICAL STUDIES

A prospective non-randomized multicenter international study evaluated the Medtronic FREESTYLE Bioprosthesis with patient follow-up out to three years. A total of 882 patients received the

bioprosthesis. Patients were evaluated preoperatively, within 30 days post-operatively at 3 to 6 months, and annually. The cumulative follow-up was 1246 patient-years with a mean follow-up of 17 months (SD = 12 months, range = 0 to 42 months).

Figure 7.1 shows the number of patients implanted by technique versus duration of follow-up and the subsequent table shows the breakdown of duration of follow-up by technique and by valve size.

Figure 7.1: Number of Patients by Duration of Follow-up and Implant Technique:
All patients implanted, approved sizes, N=882



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Implant Technique	Duration of follow-up (years)				
	0	1	2	3	3.5
	Number of patients by technique by year				
Total	882	552	348	96	1
Subcoronary	640	416	255	58	1
Full-Root	159	81	48	20	0
Root-Inclusion	83	55	45	18	0
	Number of patients by size by year				
Size					
19mm	36	22	12	4	0
21mm	149	91	57	13	0
23mm	250	156	99	26	1
25mm	236	153	99	31	0
27mm	212	130	81	22	0

Table 7.1: Patient Characteristics: Subcoronary Technique
All patients analyzed, N=631

Age at implant in years (mean \pm SD, N [min., max.]	71 \pm 8, 631 [32, 91]
Gender (% male / % female)	53% / 47%
Etiology	
Stenosis—percent of patients with stenosis alone [% (number in subgroup/N)]	43% (272/631)
Insufficiency—percent of patients with insufficiency alone [% (number in subgroup/N)]	6% (39/631)
Mixed—percent of patients with stenosis and insufficiency [% (number in subgroup/N)]	50% (318/631)
Other ¹ —percent of patients with etiology other than stenosis or insufficiency [% (number in subgroup/N)]	0% (2/631)

Note:

1. One patient had incidental replacement of a previously implanted prosthesis and one patient had endocarditis without lesion.

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Table 7.2: Patient Characteristics: Full-Root Technique
All patients analyzed: N=157

Age at implant in years (mean ± SD, N [min., max.])	70± 8, 157 [38, 87]
Gender (% male /% female)	51% /49%
Etiology	
Stenosis—percent of patients with stenosis alone [% (number in subgroup/N)]	31% (49/157)
Insufficiency—percent of patients with insufficiency alone [% (number in subgroup/N)]	21% (33/157)
Mixed—percent of patients with stenosis and insufficiency [% (number in subgroup/N)]	47% (74/157)
Other ¹ —percent of patients with etiology other than stenosis or insufficiency [% (number in subgroup/N)]	1% (1/157)

Note:

1. One patient had a dissecting ascending aortic aneurysm.

Table 7.3: Patient Characteristics: Root-Inclusion Technique
All patients analyzed: N=80

Age at implant in years (mean ± SD, N [min., max.])	69± 9, 80 [40, 90]
Gender (% male /% female)	73% /28%
Etiology	
Stenosis—percent of patients with stenosis alone [% (number in subgroup/N)]	41% (33/80)
Insufficiency—percent of patients with insufficiency alone [% (number in subgroup/N)]	11% (9/80)
Mixed—percent of patients with stenosis and insufficiency [% (number in subgroup/N)]	48% (38/80)

4.4

Table 7.4: Effectiveness Outcomes, Functional NYHA: Subcoronary Technique
 All patients analyzed: N=631, mean ± SD (number), percent (numerator/N)

Endpoint	Preoperative	3-6 Months	One Year
Functional NYHA	2.9 ± 0.6 (631)	1.2 ± 0.5 (525)	1.2 ± 0.5 (454)
I - % of pts. in NYHA class I	2% (14/631)	80% (419/525)	84% (380/454)
II - % of pts. in NYHA class II	20% (129/631)	18% (96/525)	14% (64/454)
III - % of pts. in NYHA class III	63% (400/631)	2% (10/525)	2% (8/454)
IV - % of pts. in NYHA class IV	14% (88/631)	0% (0/525)	0% (2/454)

Table 7.5: Effectiveness Outcomes, Functional NYHA: Full-Root Technique
 All patients analyzed: N=157, mean ± SD (number), percent (numerator/N)

Endpoint	Preoperative	3-6 Months	One Year
Functional NYHA	2.9 ± 0.7 (155)	1.1 ± 0.2 (114)	1.1 ± 0.3 (87)
I - % of pts. in NYHA class I	1% (2/155)	94% (107/114)	91% (79/87)
II - % of pts. in NYHA class II	20% (31/155)	6% (7/114)	9% (8/87)
III - % of pts. in NYHA class III	61% (95/155)	0% (0/114)	0% (0/87)
IV - % of pts. in NYHA class IV	17% (27/155)	0% (0/114)	0% (0/87)

Table 7.6: Effectiveness Outcomes, Functional NYHA: Root-Inclusion Technique
 All patients analyzed: N=80, mean ± SD (number), percent (numerator/N)

Endpoint	Preoperative	3-6 Months	One Year
Functional NYHA	2.7 ± 0.6 (80)	1.2 ± 0.5 (60)	1.1 ± 0.3 (54)
I - % of pts. in NYHA class I	5% (4/80)	87% (52/60)	91% (49/54)
II - % of pts. in NYHA class II	26% (21/80)	10% (6/60)	9% (5/54)
III - % of pts. in NYHA class III	68% (54/80)	3% (2/60)	0% (0/54)
IV - % of pts. in NYHA class IV	1% (1/80)	0% (0/60)	0% (0/54)

Table 7.7: Effectiveness Outcomes, Hemodynamics, Valvular Regurgitation: Subcoronary Technique
 All patients analyzed: N=631, mean ± SD (number), percent (numerator/N)

Endpoint	<30 Days	3-6 Months	One Year
Valvular Regurgitation [†]	0.3 ± 0.4 (552)	0.3 ± 0.5 (523)	0.3 ± 0.4 (456)
0 % of pts. with no Rg.	65% (358/552)	62% (326/523)	65% (296/456)
<1+ % of pts. with <mild Rg.	15% (82/552)	17% (87/523)	20% (92/456)
1+ % of pts. with mild Rg.	20% (108/552)	19% (101/523)	13% (61/456)
2+ % of pts. with mod Rg.	1% (3/552)	2% (8/523)	1% (5/456)
3+/4+ % of pts. with mod/severe	0% (1/552)	0% (1/523)	0% (2/456)

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Notes:

Rg. = Regurgitation

1. The data reflect regurgitation noted at all locations combined. Data coded as "trivial/mild" were included in the category "<1+, <mild regurgitation." Data in the category "<1+" were coded as "0.5" for the calculation of mean ± SD.

Table 7.8: Effectiveness Outcomes, Hemodynamics, Valvular Regurgitation:

Full-Root Technique

All patients analyzed: N=157, mean ± SD
(number), percent (numerator/N)

Endpoint	<30 Days	3-6 Months	One Year
Valvular Regurgitation ^a	0.1 ± 0.3 (131)	0.1 ± 0.3 (113)	0.1 ± 0.2 (90)
0% of pts. with no Rg.	86% (113/131)	87% (98/113)	87% (78/90)
<1+ % of pts. with <mild Rg.	8% (10/131)	8% (9/113)	11% (10/90)
1+ % of pts. with mild Rg.	5% (7/131)	4% (5/113)	2% (2/90)
2+ % of pts. with mod Rg.	1% (1/131)	1% (1/113)	0% (0/90)
3+/4+ % of pts. with mod severe/severe Rg.	0% (0/131)	0% (0/113)	0% (0/90)

Notes:

Rg. = Regurgitation

1. The data reflect regurgitation noted at all locations combined. Data coded as "trivial/mild" were included in the category "<1+, <mild regurgitation." Data in the category "<1+" were coded as "0.5" for the calculation of mean ± SD.

Table 7.9: Effectiveness Outcomes, Hemodynamics, Valvular Regurgitation:
Root-Inclusion Technique
All patients analyzed: N=80, mean ± SD
(number), percent (numerator/N)

Endpoint	<30 Days	3-6 Months	One Year
Valvular Regurgitation ^a	0.2 ± 0.4 (75)	0.1 ± 0.3 (63)	0.2 ± 0.3 (51)
0% of pts. with no Rg.	77% (58/75)	79% (50/63)	76% (39/51)
<1+ % of pts. with <mild Rg.	15% (11/75)	14% (9/63)	16% (8/51)
1+ % of pts. with mild Rg.	5% (4/75)	6% (4/63)	8% (4/51)
2+ % of pts. with mod Rg.	3% (2/75)	0% (0/63)	0% (0/51)
3+/4+ % of pts. with mod severe/severe Rg.	0% (0/75)	0% (0/63)	0% (0/51)

Notes:

Rg. = Regurgitation

1. The data reflect regurgitation noted at all locations combined. Data coded as "trivial/mild" were included in the category "<1+, <mild regurgitation." Data in the category "<1+" were coded as "0.5" for the calculation of mean ± SD.

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Table 7.10: Effectiveness Outcomes, Hemodynamics, Mean Pressure Gradient: Subcoronary Technique
 All patients analyzed: N=631, number in subgroup/N, mean ± SD [min., max.]

Endpoint	<30 Days	3-6 Months	One Year
Mean Pressure Gradient (mmHg)			
19mm	19/27, 17.6 ± 7.6 [8.0, 42.0]	19/27, 12.0 ± 5.7 [2.0, 23.0]	18/27, 11.7 ± 4.7 [5.0, 19.0]
21mm	100/117, 14.6 ± 8.1 [1.0, 48.0]	91/117, 9.0 ± 6.2 [1.0, 47.0]	83/117, 9.8 ± 7.4 [0.8, 51.0]
23mm	165/191, 12.9 ± 6.9 [2.0, 39.0]	156/191, 8.9 ± 5.9 [1.0, 35.0]	138/191, 8.8 ± 6.8 [0.0, 57.0]
25mm	145/167, 9.1 ± 4.6 [1.0, 28.0]	146/167, 5.5 ± 3.3 [1.0, 19.0]	119/167, 5.1 ± 3.3 [0.0, 18.0]
27mm	112/129, 7.3 ± 4.1 [1.0, 22.0]	110/129, 5.0 ± 3.7 [1.0, 30.0]	92/129, 4.4 ± 2.9 [0.7, 13.0]

Table 7.11: Effectiveness Outcomes, Hemodynamics, Mean Pressure Gradient: Full-Root Technique
 All patients analyzed: N=157, number in subgroup/N, mean ± SD [min., max.]

Endpoint	<30 Days	3-6 Months	One Year
Mean Pressure Gradient (mmHg)			
19mm	7/7, 11.9 ± 6.0 [6.0, 23.0]	7/7, 13.4 ± 6.7 [7.0, 27.0]	5/7, 16.8 ± 7.4 [9.0, 27.1]
21mm	14/21, 7.8 ± 3.4 [2.0, 14.0]	12/21, 7.6 ± 3.5 [2.0, 14.0]	9/21, 7.2 ± 4.0 [3.0, 14.0]
23mm	20/32, 6.8 ± 3.8 [0.9, 13.0]	20/32, 5.4 ± 3.4 [1.0, 12.0]	13/32, 7.1 ± 3.7 [1.6, 14.0]
25mm	31/35, 4.9 ± 2.9 [1.0, 12.0]	29/35, 4.2 ± 2.9 [1.0, 12.0]	23/35, 4.5 ± 3.4 [1.0, 17.0]
27mm	59/62, 4.4 ± 3.4 [1.0, 20.0]	46/62, 3.8 ± 2.9 [0.7, 15.0]	38/62, 3.2 ± 1.8 [1.0, 8.0]

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Table 7.12: Effectiveness Outcomes, Hemodynamics, Mean Pressure Gradient: Root-Inclusion Technique
 All patients analyzed: N=80, number in subgroup/N, mean ± SD [min., max.]

Endpoint	<30 Days	3-6 Months	One Year
Mean Pressure Gradient (mmHg)			
21mm	4/5, 12.3 ± 7.0 [3.0, 20.0]	3/5, 8.0 ± 2.6 [6.0, 11.0]	2/5, 9.0 ± 1.4 [8.0, 10.0]
23mm	21/25, 13.8 ± 10.7 [2.0, 52.0]	17/25, 10.3 ± 12.1 [2.0, 54.0]	14/25, 8.7 ± 8.8 [2.0, 36.0]
25mm	29/30, 9.6 ± 6.7 [2.0, 28.0]	25/30, 8.2 ± 6.7 [2.0, 29.0]	17/30, 7.6 ± 6.8 [2.0, 29.0]
27mm	19/20, 6.4 ± 3.4 [2.0, 14.0]	18/20, 4.4 ± 2.4 [1.0, 8.0]	15/20, 3.7 ± 2.2 [1.0, 8.0]

The expected orifice area indexed to body surface area in an adult should be greater than or equal to 1.5 cm²/m². The following effective orifice area data are not indexed to body surface area.

Table 7.13: Effectiveness Outcomes, Hemodynamics, Effective Orifice Area: Subcoronary Technique
 All patients analyzed: N=631, number in subgroup/N, mean ± SD [min., max.]

Endpoint	<30 Days	3-6 Months	One Year
Effective Orifice Area (cm²)			
19mm	19/27, 0.9 ± 0.2 [0.5, 1.4]	19/27, 1.1 ± 0.3 [0.6, 1.7]	18/27, 1.1 ± 0.3 [0.7, 1.7]
21mm	97/117, 1.3 ± 0.4 [0.5, 2.4]	91/117, 1.5 ± 0.5 [0.8, 4.3]	82/117, 1.4 ± 0.4 [0.4, 3.1]
23mm	160/191, 1.4 ± 0.5 [0.5, 3.7]	154/191, 1.7 ± 0.5 [0.6, 3.6]	137/191, 1.7 ± 0.5 [0.8, 3.9]
25mm	143/167, 1.8 ± 0.6 [0.4, 3.9]	146/167, 2.0 ± 0.5 [0.9, 3.5]	119/167, 2.0 ± 0.5 [0.8, 3.5]
27mm	110/129, 2.2 ± 0.7 [0.8, 5.1]	109/129, 2.4 ± 0.6 [1.2, 4.1]	92/129, 2.5 ± 0.7 [1.3, 4.4]

Table 7.14: Effectiveness Outcomes, Hemodynamics, Effective Orifice Area: Full-Root Technique
 All patients analyzed: N=157, number in subgroup/N, mean ± SD [min., max.]

Endpoint	<30 Days	3-6 Months	One Year
Effective Orifice Area (cm²)			
19mm	7/7, 1.3 ± 0.4 [0.5, 1.7]	7/7, 1.1 ± 0.3 [0.6, 1.5]	5/7, 1.0 ± 0.1 [0.9, 1.1]
21mm	14/21, 1.5 ± 0.6 [0.9, 3.3]	12/21, 1.7 ± 0.4 [1.2, 2.3]	9/21, 1.4 ± 0.3 [1.1, 1.9]
23mm	19/32, 1.7 ± 0.4 [0.7, 2.4]	19/32, 1.8 ± 0.5 [1.2, 3.0]	13/32, 2.0 ± 0.5 [1.5, 3.3]
25mm	31/35, 2.1 ± 0.6 [1.1, 3.8]	29/35, 2.1 ± 0.5 [1.1, 3.8]	24/35, 2.2 ± 0.6 [1.3, 3.5]
27mm	59/62, 2.1 ± 0.6 [1.1, 4.0]	46/62, 2.3 ± 0.5 [1.3, 3.3]	37/62, 2.4 ± 0.7 [1.3, 4.3]

Table 7.15: Effectiveness Outcomes, Hemodynamics, Effective Orifice Area: Root-Inclusion Technique
 All patients analyzed: N=80, number in subgroup/N, mean ± SD [min., max.]

Endpoint	<30 Days	3-6 Months	One Year
Effective Orifice Area (cm²)			
21mm	4/5, 1.6 ± 0.8 [1.0, 2.8]	2/5, 1.4 ± 0.2 [1.3, 1.5]	2/5, 1.0 ± 0.1 [0.9, 1.2]
23mm	21/25, 1.6 ± 0.6 [0.8, 3.0]	16/25, 1.8 ± 0.5 [0.9, 3.0]	14/25, 1.9 ± 0.4 [1.1, 3.1]
25mm	29/30, 1.9 ± 0.8 [0.9, 3.4]	22/30, 2.2 ± 0.8 [1.2, 3.8]	17/30, 2.2 ± 0.8 [1.0, 3.6]
27mm	19/20, 2.4 ± 0.7 [1.4, 4.0]	18/20, 2.7 ± 0.7 [1.8, 4.7]	15/20, 3.0 ± 0.9 [1.7, 5.0]

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8. INDIVIDUALIZATION OF TREATMENT

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

8.1 Specific Patient Populations

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

- patients in whom the Medtronic FREESTYLE Bioprosthesis has been implanted for longer than 3 years (refer to sections 6 and 7, Adverse Events and Clinical Studies);
- patients who are pregnant;
- nursing mothers;
- patients with chronic renal failure;
- patients with aneurysmal aortic degenerative conditions, e.g. cystic medial necrosis, Marfan's Syndrome.

The clinical study of the Medtronic FREESTYLE Bioprosthesis has yielded limited data for the following implant techniques and sizes:

- Full-Root implant technique in the 19mm, 21mm and 23mm sizes (refer to sections 6 and 7, Adverse Events and Clinical Studies);
- Root-inclusion implant technique in the 19mm and 21mm sizes (refer to sections 6 and 7, Adverse Events and Clinical Studies).

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9. PATIENT COUNSELING INFORMATION

Patients may require anticoagulation and/or antiplatelet therapy for an indefinite period based on the patient's condition.

Patients with bioprosthetic valves who undergo dental or potentially bacteremic procedures must be considered for prophylactic antibiotic therapy.

10. HOW SUPPLIED

10.1 Available Sizes

The Medtronic FREESTYLE Bioprosthesis is designed only for the aortic position and is available in the following implantation diameters: 19mm, 21mm, 23mm, 25mm and 27mm.

10.2 Packaging

The Medtronic FREESTYLE Bioprosthesis is supplied STERILE in a buffered 0.2% glutaraldehyde storage solution. Sterility is not compromised if the package is unopened and undamaged. The outside of the container is NOT sterile and should not be placed in the sterile field.

10.3 Storage

The Medtronic FREESTYLE 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.

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The storage life of the Medtronic FREESTYLE 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

The function of a stentless bioprosthetic valve is sensitive to surgical implantation technique. The Medtronic FREESTYLE Aortic Root Bioprosthesis is packaged as a single device that is modified at operation for insertion with one of three techniques to replace the native valve leaflets with the subcoronary technique, to replace the entire valve mechanism with the root-inclusion technique, or to replace the entire valve mechanism as well as the aortic root with the full-root technique.

Implanting physicians must be familiar with the techniques for implanting an unstented bioprosthesis. These techniques are similar to those required for allograft implantation. Medtronic has established a training program which provides surgeons with instructions on the implantation of the FREESTYLE bioprosthesis. Contact Medtronic Heart Valves, Inc. or your local Sales Representative for further information regarding this program.

11.2 Device Features

Features of the Medtronic FREESTYLE Bioprosthesis include surgeon's flags, which are located 120 degrees apart at the inflow aspect of the bioprosthesis to facilitate uniform placement of sutches for the proximal suture line. Colored stitching, circumferentially placed around the cloth cover, indicates the upper

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limit for insertion of the proximal sutures. The size of the bioprosthesis is the outside diameter at the inflow edge. The Medtronic FREESTYLE Bioprosthesis is designed for the aortic position only and is available in the following implantation diameters: 19mm, 21mm, 23mm, 25mm, and 27mm.

11.3 Handling and Preparation Instructions

Proper size selection of the bioprosthesis is critical to heart valve replacement. The internal diameter of the patient's aortic root at the annulus and supracommissural areas may be measured preoperatively, during diastole, using angiographic and/or echocardiographic techniques. The size selection of a Medtronic FREESTYLE Bioprosthesis is aided by the use of the Medtronic FREESTYLE Aortic Obturator (Model 7990). Use only Medtronic FREESTYLE Aortic Obturators to select the appropriate bioprosthesis size. For further information refer to the Medtronic FREESTYLE Aortic Obturator Instructions for Use.

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

The exterior of the device container and lid are nonsterile. The circulating nurse should examine the seal to verify that the container has not been damaged or previously opened. Remove and discard the seal. Turn the lid counterclockwise, and open the container (Figures 1 and 2).

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.

The bioprosthesis and all internal packaging components within the container are sterile and must be handled accordingly. With the

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thumb and index finger, grasp the finger slots of the retainer and slowly lift it out of the container, allowing for drainage of the glutaraldehyde storage solution (Figure 3).

Unscrew the retainer cap and place the bioprosthesis directly into the free hand (Figures 4 and 5).

Have an assistant record the identification number of the bioprosthesis in the patient's record.

Carefully cut the identification tag from the bioprosthesis and discard the tag (Figure 6).

NOTE: Be careful not to cut the cloth or tissue of the bioprosthesis when removing the identification tag. Remove any remnants of the identification tag suture from the bioprosthesis.

Submerge the bioprosthesis into the first rinse basin. Do not touch the leaflets of the bioprosthesis or squeeze the bioprosthesis during the rinsing procedure. Gently swirl the bioprosthesis in the solution for a minimum of two minutes in each of the three previously prepared rinse basins (Figure 7). The bioprosthesis should remain in the third rinse basin until required by the surgeon.

11.4 Device Implantation

The total root design of the Medtronic FREESTYLE Bioprosthesis allows the physician to select a bioprosthesis configuration which meets patient indications and surgical technique preference. The provided information reflects the implant techniques utilized during the clinical study:

Subcoronary Technique: The native aortic valve is excised for subcoronary implantation of the bioprosthesis. The bioprosthesis is trimmed of excess aorta. The coronary sinuses are scalloped for

clearance of native coronary ostia commencing at the sinotubular junction. A sinus may be left intact on the bioprosthesis for a modified subcoronary technique.

Full-Root Technique: The entire native aortic root and aortic leaflets are excised and replaced with the FREESTYLE Bioprosthesis. The native coronary arteries are excised from the aortic root along with a button of the proximal aorta. The bioprosthesis is sutured to the annulus and two of the three bioprosthetic sinuses are excised to accommodate the reattachment of the native coronary arteries.

Root-Inclusion Technique: After the native aortic valve leaflets are excised, the bioprosthesis is placed within the native aorta, giving the appearance of a tube within the native aorta. To allow clearance for the native coronary ostia, two of the three sinuses are excised leaving buttonholes in the bioprosthesis. The sinotubular junction remains intact. **NOTE:** Safety and effectiveness data, from the clinical study, are not available for the 19mm and 21mm sizes utilizing the root inclusion technique (refer to sections 6 and 7, Adverse Events and Clinical Studies).

Care should be exercised when placing sutures through the sewing rim and aortic wall to prevent stitching through, or perforation of, the cusps of the bioprosthesis. The colored suture line at the inflow identifies the area for placing sutures in the sewing rim. Sutures should only be placed proximal to this demarcation line.

During implantation, do not allow the tissue of the bioprosthesis to dry. Continuous submersion or irrigation is required.

Do not use cutting needles as they may cause structural damage to the bioprosthesis.

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Use extreme caution if tailoring the bioprosthesis to fit the anatomical requirements of a particular patient's coronary sinuses or ostia. Improper trimming may result in immediate or delayed damage to and/or dysfunction of the bioprosthesis.

If the bioprosthetic root is tailored to accommodate the coronary ostia, retained commissure posts should be fixed to the patient's aortic root 2 to 3 mm above the native commissure attachments to prevent leaflet prolapse with aortic regurgitation.

The potential for damage to the bioprosthesis should be considered before passing surgical instruments.

11.5 Catheterization

Passage of a catheter through any bioprosthesis may damage the valve and is, therefore, not recommended.

11.6 Accessories

Use only Medtronic FREESTYLE Aortic Obturators (Model 7990) and the Medtronic Handle (Model 0791) to determine the appropriate Medtronic FREESTYLE Bioprosthesis size.

NOTE: Do not use other manufacturer's valve obturators, or obturators for another Medtronic prosthesis to size the Medtronic FREESTYLE Bioprosthesis.

11.7 Return of Explanted Bioprosthetic Valves

Medtronic, Inc. is interested in obtaining recovered Freestyle 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 are available by contacting

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Medtronic, Inc. distribution centers and your Medtronic Sales Representative. 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.

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 you, the physician, may choose to provide to your patient prior to discharge. Copies of these pamphlets may be obtained from your Medtronic Sales Representative.

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13. REFERENCES

1. Girardot JM, Girardot MN, Gott JP, Eberhardt C, Myers D, Torrianni M. Preclinical Testing for Antimineralization Treatments of Heart Valve Bioprotheses. In: Wise DL, ed. *Encyclopedic Handbook of Biomaterials and Bioengineering*, Part B: Marcel Dekker Inc; 1995; xvii, 851 and II:xv, 939.
2. Sintek CF, Fletcher AD, Khonsari S. Stentless porcine aortic root: Valve of Choice for the Elderly Patient with Small Aortic Root. *J Thorac Cardiovasc Surg.* 1995; 109 (5): 871-876.
3. Westaby S, Amarasena N, Ormerod O, Amarasena GAC, Pillai R. Aortic Valve Replacement with the Freestyle Stentless Xenograft. *Ann Thorac Surg.* 1995; 60 (2):422-427.

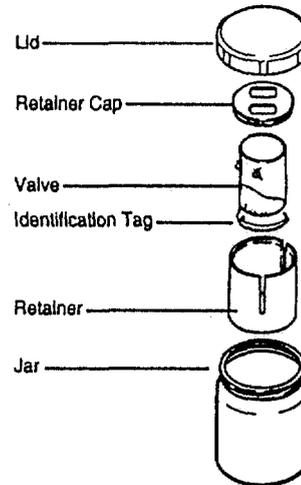


Figure 1. Package Components of the FREESTYLE Aortic Root Bioprosthesis

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Figure 2. Opening Valve Jar

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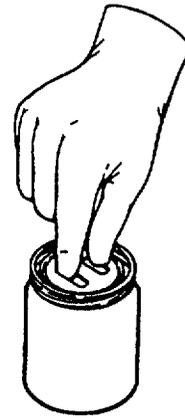


Figure 3. Removal of Retainer from Jar

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Figure 4. Retainer Cap Removal

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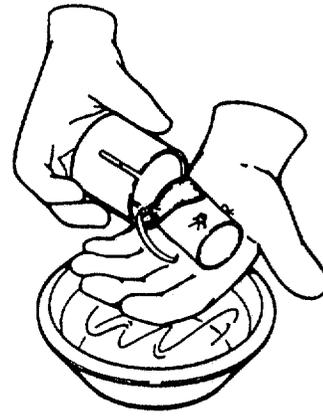


Figure 5. Valve Removal from Retainer

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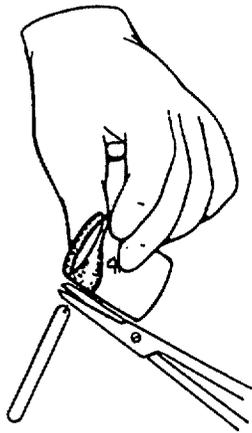


Figure 6. Release of Identification Tag (Serial Number)

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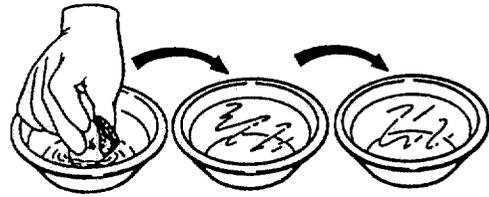


Figure 7. Rinsing of FREESTYLE Aortic Root Bioprosthesis

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