Medtronic

URGENT FIELD SAFETY NOTICE

Sizing of Medtronic Mosaic™ Aortic Bioprosthesis

Model Number: 305

Updated Sizing Recommendations

January 09, 2014

Medtronic reference: **FA599**

Dear Physician, Health Care Professional (Hospital Administrator, Risk Manager),

This notification is to provide you with important information regarding the sizing of the Medtronic Mosaic™ Porcine Aortic Bioprosthesis (all sizes and configurations, Standard and Ultra). Medtronic has received infrequent reports of higher-than-expected transvalvular gradients occurring post implant. These reports have NOT been associated with the Mosaic Mitral™ Bioprosthesis (Model 310).

The higher-than-expected transvalvular gradients (> 25 mmHg) of the Mosaic Aortic Bioprosthesis have occurred at a rate of 0.33 percent (3.3 reports per 1000 aortic implants). A subset of these valves was explanted within five years of implantation at an overall occurrence rate of 0.1 percent (1 explant per 1000 aortic implants).

Medtronic has determined that the practice of substantial oversizing can lead to cases of higher-than -expected transvalvular gradients. Specifically, considerable oversizing, or implanting a valve substantially larger than the native aortic annulus, may result in the alteration of normal leaflet movement as blood flowing through the native annulus may not properly match the size and/or shape of the inflow of the Mosaic Aortic Bioprosthesis. Further, Medtronic has concluded that the current Mosaic Aortic Bioprosthesis sizing chart (Indexed effective orifice area (iEOA) chart) and Obturators/Sizers may contribute in some cases to the selection of a larger than optimal Mosaic Aortic Bioprosthesis.

To optimize sizing, Medtronic is implementing the following actions:

1. Medtronic has modified the iEOA Mosaic Aortic Bioprosthesis sizing chart. It is recommended to begin using the updated iEOA sizing chart.
2. Medtronic has modified the current Mosaic Obturators/Sizers to align with the updated sizing chart. The IFU for the modified Mosaic Obturators/Sizers has been updated to include the new sizing chart (iEOA chart). It is recommended to use the modified Mosaic Obturators/Sizers.
3. Medtronic will discontinue distribution of the previous Mosaic Obturators/ Sizers and iEOA sizing chart.

Advice on action to be taken by the user:

Medtronic recommends surgeons continue to remain diligent in selecting the appropriate size of Mosaic Aortic Bioprosthesis. Adoption of the updated Mosaic Aortic Bioprosthesis sizing chart (iEOA chart) and Mosaic Obturators/Sizers will facilitate optimal aortic valve size selection.

Medtronic is not making any specific patient management recommendations. Surgeons and cardiologists should continue to follow their valve patients per their usual practice and in accordance with published guidelines.

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Your Medtronic Field Representative will be contacting you about receiving a new Mosaic Aortic Obturator/Sizer set and sizing chart. If you would prefer to order the new Mosaic Aortic Obturator/Sizer set please contact your Medtronic Field Representative.

The Competent Authority of your country has been informed of this action.

Please share this notification with others in your organization as appropriate. We appreciate your review of this notification and apologize for the inconvenience that it may cause. If you have any questions, please contact your Medtronic Field Representative.

Sincerely,

Att: Updated iEOA Sizing Chart

Patient-Prosthesis Matching

In Vivo Indexed Effective Orifice Area (IEOA)

Medtronic

It is recommended that the Medtronic Mosaic Cinch®/Mosaic Ultra® Aortic Sizers be used to determine the appropriate Medtronic Mosaic® bioprosthetic aortic valve size. Refer to the Instructions For Use for sizing instructions.

The Indexed Effective Orifice Area (iEOA) chart may be utilized to identify the aortic valve size to avoid patient-prosthesis mismatch.[2] The iEOA chart information is intended for reference purposes only.

The final valve size selection should be based on the sizer criteria and the surgeon clinical judgment after taking into account the severity of the aortic stenosis preoperatively, how physically active the patient is likely to be postoperatively, patient age, sex, LV function and size, and hypertrophy.[4]

To assist in avoiding patient-prosthesis mismatch, select a valve size that achieves an indexed effective orifice area of ≥ 0.75 cm^2/m^2. If the indexed effective orifice area is < 0.75 cm^2/m^2 (identified in red), consideration should be given to an annular enlargement procedure.

The risk-to-benefit ratio of an annular enlargement procedure to avoid moderate PPM is acceptable in younger patients who can be expected to engage in vigorous physical activities, whereas it would not be prudent in an elderly patient who is sedentary.[4]

KEY

To Maximize Patient-Prosthesis Matching[1]

1. Determine patient's body surface area (BSA)
2. Using the chart, select valve size with iEOA ≥ 0.75 to assist in avoiding patient-prosthesis mismatch

≥0.75 | <0.75

IEOA = EOA/BSA

References

1. Rao V, Jamieson WRE, Ivanov J, Armstrong S, David TE. Prosthesis-patient mismatch affects survival after aortic valve replacement. *Circulation*. 2000;102(suppl III):III-5–III-9
2. Daneshvar S, Rahimtoola SH.Valve Prosthesis-patient mismatch (VP-PM):A long-term perspective. Journal American College of Cardiology. 2012;60:1123-35.
3. Fradet GJ, Bleese N, Burgess J, and Cartier PC. Mosaic valve international clinical trial: Early performance results. Ann Thorac Surg. 2001;71:S273-277.
4. Svensson LG, Adams DH, Bonow RO, et. al. Aortic Valve and Ascending Aorta Guidelines for Management and Quality Measures. Ann Thorac Surg. 2013;95:1-66.

Mosaic®
Aortic Bioprosthesis

Valve Size

	19mm (n=4)	21mm (n=198)	23mm (n=440)	25mm (n=317)	27mm (n=110)	29mm (n=22)
EOA (cm^2)*	1.20	1.30	1.50	1.80	2.00	2.10

Patient BSA (m^2)						
1.0	1.20	1.30	1.50	1.80	2.00	2.10
1.1	1.09	1.18	1.36	1.64	1.82	1.91
1.2	1.00	1.08	1.25	1.50	1.67	1.75
1.3	0.92	1.00	1.15	1.38	1.54	1.62
1.4	0.86	0.93	1.07	1.29	1.43	1.50
1.5	0.80	0.87	1.00	1.20	1.33	1.40
1.6	0.75	0.81	0.94	1.13	1.25	1.31
1.7	0.71	0.76	0.88	1.06	1.18	1.24
1.8	0.67	0.72	0.83	1.00	1.11	1.17
1.9	0.63	0.68	0.79	0.95	1.05	1.11
2.0	0.60	0.65	0.75	0.90	1.00	1.05
2.1	0.57	0.62	0.71	0.86	0.95	1.00
2.2	0.55	0.59	0.68	0.82	0.91	0.95
2.3	0.52	0.57	0.65	0.78	0.87	0.91
2.4	0.50	0.54	0.63	0.75	0.83	0.88
2.5	0.48	0.52	0.60	0.72	0.80	0.84
2.6	0.46	0.50	0.58	0.69	0.77	0.81
2.7	0.44	0.48	0.56	0.67	0.74	0.78

Estimated *In Vivo* Indexed Effective Orifice Area (IEOA)

*1 year hemodynamic data[3]

Mosaic® Porcine Bioprosthesis
Indications: For the replacement of malfunctioning native or prosthetic aortic and/or mitral heart 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.

DO NOT oversize. Implanting too large a valve in a patient can lead to stent distortion and/or valve inflow obstruction and an increased risk for stenosis, regurgitation, or reduced valve durability.

Implanting too small a valve in a patient can lead to an increased risk for stenosis.

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

www.medtronic.com

World Headquarters
Medtronic, Inc.
710 Medtronic Parkway
Minneapolis, MN 55432-5604
USA
Tel: (763) 514-4000
Fax: (763) 514-4879

Medtronic USA, Inc.
Toll-free: 1 (800) 328-2518
(24-hour technical support for physicians and medical professionals)

LifeLine CardioVascular Technical Support
Tel: (877) 526-7890
Tel: (763) 526-7890
Fax: (763) 526-7888
E-mail: rs.cstechsupport@medtronic.com

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