

## Important

### Medical Device Information regarding Mitroflow Model 12, LXA and DL

6 May 2015

Dear Doctor and valued customers,

#### Summary

This letter is to provide you with a revised Mitroflow EOAI (Effective Orifice Area Index) chart that is based on recent published *in-vivo* data, instead of the current chart that is based on *in-vitro* data.

#### Description and Clinical Implications

Sorin Group (Sorin) developed this updated EOAI chart for the Mitroflow models that are the object of this letter since the current *in-vitro* EOAI chart may not accurately reflect the complexity of physiologic hemodynamics.

The revised EOAI chart is based on published data of hemodynamic performance from a large number of patients implanted with the Mitroflow valve<sup>1</sup> and a widely accepted paper that provides accepted values for each level of patient prosthesis mismatch, based on projected EOAI<sup>2</sup> (see Appendix 1). The EOAs cited in this chart were based on a retrospective study of 1,135 patients implanted with Mitroflow aortic bioprostheses at the Mayo Clinic (Rochester, Minnesota, USA) between June 2007 and December 2012<sup>1</sup>. The reference publication<sup>2</sup> from Pibarot and Dumesnil provides generally accepted guidelines for the severity of PPM based on projected EOAI values:  $\geq 0.85 \text{ cm}^2/\text{m}^2$ , no PPM;  $> 0.65$  and  $< 0.85 \text{ cm}^2/\text{m}^2$ , moderate PPM;  $\leq 0.65 \text{ cm}^2/\text{m}^2$ , severe PPM.

These updated EOAI chart based on *in-vivo* data was developed to provide a more accurate indication of the potential for the development of PPM following implantation of a specific Mitroflow valve size, over the range of patient body surface area. However, please note that this chart is not intended to replace standard clinical judgment, best surgical practices for aortic

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<sup>1</sup> Ugur M, Suri RM, Daly RC, Dearani JA, Park SJ, Joyce LD, Burkhart HM, Greason KL, Schaff HV. Comparison of early hemodynamic performance of 3 aortic valve bioprostheses. *J Thorac Cardiovasc Surg.* 2014 Jan 15. pii: S0022-5223(14)00027-0.

<sup>2</sup> Pibarot P, Dumesnil JG. Hemodynamic and clinical impact of prosthesis-patient mismatch in the aortic valve position and its prevention. *J Am Coll Cardiol.* 2000 Oct;36(4):1131-41



valve size selection, or the information provided by the manufacturer in the product Instructions for Use (IFU). The following standard formula for calculating the EOAI was used in the attached chart:

$$EOAI = \frac{EOA}{BSA}$$

where EOA represents the effective orifice area (cm<sup>2</sup>) of the valves to be implanted and BSA represents the body surface area (m<sup>2</sup>) of the patient. BSA may be calculated using the following formula:

$$BSA = 0.007184 \times H^{0.725} \times M^{0.425}$$

where H is the patient height (cm) and M is the patient weight (kg).

### Recommendations

Please make sure all clinical staff is aware that EOAI chart provided by Sorin Group has been updated, see Appendix 1

If you need any clarification about the content of this letter, please contact the Sorin Group point of contact indicated below.

Contact reference person:

For questions regarding this Notice, please contact [REDACTED], Director QA, Sorin Group Canada Inc.

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Thank you for your cooperation in this matter. Sorin Group is committed to provide quality products and service to its customers.

Sorin group has reviewed these recommendations with an independent panel of physicians and they support the *in-vivo* EOAI chart.

Sorin Group recognizes the impact of this communication for both you and your patients and wants to reassure you that patient safety remain our primary concern. If you have additional



questions regarding this communication or would like to report clinical events, please contact Heart Valve Feedback at [hv.feedback@sorin.com](mailto:hv.feedback@sorin.com)

Sincerely,



Director Quality Assurance  
Sorin Group Canada, Inc.

## Appendix 1

### Mitroflow – EOAI Chart ( In Vivo Data)

#### MITROFLOW – EOAI CHART

Valve Size		19	21	23	25
EOA (cm <sup>2</sup> )		1.2 <sup>a</sup>	1.5 <sup>a</sup>	1.8 <sup>a</sup>	2.3 <sup>a</sup>
BSA (m <sup>2</sup> )	1	1.20	1.50	1.80	2.30
	1.1	1.09	1.36	1.64	2.09
	1.2	1.00	1.25	1.50	1.92
	1.3	0.92	1.15	1.38	1.77
	1.4	0.86	1.07	1.28	1.64
	1.5	0.80	1.00	1.20	1.53
	1.6	0.75	0.94	1.13	1.44
	1.7	0.71	0.88	1.06	1.35
	1.8	0.67	0.83	1.00	1.28
	1.9	0.63	0.79	0.95	1.21
	2	0.60	0.75	0.90	1.15
	2.1	0.57	0.71	0.86	1.10
	2.2	0.55	0.68	0.82	1.05
	2.3	0.52	0.65	0.78	1.00
	2.4	0.50	0.63	0.75	0.96
	2.5	0.48	0.60	0.72	0.92

- EOAI ≥ 0.85 No Patient-Prosthesis Mismatch<sup>b</sup>
- 0.65 < EOAI < 0.85 Moderate Patient-Prosthesis Mismatch<sup>b</sup>
- EOAI ≤ 0.65 Severe Patient-Prosthesis Mismatch<sup>b</sup>

a. Ugur M, Suri RM, Daly RC, Dearani JA, Park SJ, Joyce LD, Burkhart HM, Greason KL, Schaff HV. Comparison of early hemodynamic performance of 3 aortic valve bioprostheses. *J Thorac Cardiovasc Surg.* 2014 Jan 15. pii: S0022-5223(14)00027-0.

b. Pibarot P, Dumesnil JG. Hemodynamic and clinical impact of prosthesis-patient mismatch in the aortic valve position and its prevention. *J Am Coll Cardiol.* 2000 Oct;36(4):1131-41.

