Letters to the Editor

The Editor welcomes submissions for possible publication in the Letters to the Editor section that consist of commentary on an article published in the Journal or other relevant issues. Authors should:

- Include no more than 500 words of text, three authors, and five references
- Type with double-spacing
- See <http://jtcs.ctsnetjournals.org/misc/ifora.shtml> for detailed submission instructions.
- Submit the letter electronically via jtcvs.editorialmanager.com.

Letters commenting on an article published in the JTCVS will be considered if they are received within 6 weeks of the time the article was published. Authors of the article being commented on will be given an opportunity to offer a timely response (2 weeks) to the letter. Authors of letters will be notified that the letter has been received. Unpublished letters cannot be returned.

Prosthetic cardiac valve replacement *To the Editor:*

The US Food and Drug Administration (FDA) has become aware of a problem associated with cardiac valve prosthetic replacement arising from mismatch between annulus sizing devices and the labeled dimension of prostheses. Anecdotal reports suggest that discrepancies between the labeled size of prostheses and the dimensions of the specific sizer may have compromised seating of selected valve prostheses.¹ Christakis and colleagues² documented discrepancies of as much as 8 mm between the labeled size of a particular prosthesis and the external diameter of the sewing cuff. Considerable variation was also found between the diameters of sewing cuffs for valves labeled as similar in size by different manufacturers. Although these discrepancies may not in themselves be relevant to the implantation procedure when the appropriately matched device-specific sizer is used, the use of generic or so-called universal sizers or of sizers designed for other prostheses, even if from the same manufacturer, may result in selection of an oversized valve. At best such an occurrence will require discarding a device before suture attachment because of body fluid contamination. A more serious consequence occurs when the mismatch is not recognized until the attempt to seat the prosthesis after suture placement.

To assess the pervasiveness of this problem with valve sizers, the Society of Thoracic Surgeons, in cooperation with the FDA, surveyed a cohort of 200 cardiac surgeons. One hundred six responders to a mailed questionnaire identified problems with manufacturer-supplied sizers in 31 instances and with universal sizers in 7 cases. The responders also indicated knowledge of similar problems experienced by other surgeons in 52 instances.

The intention of this communication is to alert surgeons to the FDA's concerns regarding the problem of valve and sizer mismatch. The frequency of occurrence suggests a need for remedial prosthetic labeling that accurately and uniformly across

devices describes both sewing cuff external dimensions and orifice area. Tight manufacturing controls should ensure that the prosthetic sewing cuff dimension matches the labeled size within specified tolerances that provide confidence that they are accurately reflected by the sizers used to measure the cardiac valve annulus.

Because of the FDA's concerns, surgeons are cautioned to use only sizers labeled for use with the specific prosthetic valve to be implanted. In addition, it is advised that selection of a satisfactory device fit be confirmed by testing the prosthesis within the annulus before insertion of sewing cuff sutures.

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2. Christakis GT, Butth KJ, Goldman BS, Freme SE, Rao V, Cohen G, et al. Inaccurate and misleading valve sizing: a proposed standard for valve size nomenclature. *Ann Thorac Surg.* 1998;66:1198-203.
doi:10.1016/S0022-5223(03)00120-X

Resection of pulmonary arteriovenous fistula

To the Editor:

The article on pulmonary arteriovenous fistula by Schröder and colleagues¹ was of interest to me, as was the follow-up Letter to the Editor by Fell.²

I have treated a number of patients with pulmonary arteriovenous fistulas through the years, including in particular a family congenitally affected for 4 generations. Initially, in the early 1970s, I performed primary resection of the fistulous lesions without removal of additional lung tissue.