were derived from a commercial company and were often collected by sales and product persons employed by this company. There was no doctor or investigator accountability for the accuracy of procedure reporting of most of the cases. Hence, despite an aggressive effort to capture all misaligned deployment events, this report may represent an under reporting. Most misalignment events have no immediate adverse clinical sequel, so not all are reported or recognized. Because imaging studies were not yet available for most of the events reported in the postapproval phase of the data collection process, a complete analysis of the causes of those misalignment events has not yet been possible. In addition, no data are currently available on the long-term outcome of patients with these misaligned grafts.

## CONCLUSION

Based on a thorough review of all reported cases of misaligned deployment of the Talent TSG, we believe that it is an unusual phenomenon that tends to occur in the context of specific well-defined circumstances and rarely has immediate clinical implications. It often occurs with the use of larger-diameter grafts placed in tortuous aortic anatomy. Attention to deployment technique along with proper patient selection, perioperative imaging, and case planning can help to identify the patients in whom misaligned deployment is more likely to occur and prepare physicians for using effective measures to prevent these events. Future device development is underway to prevent this phenomenon in the form of a "tip capture," which involves constriction of the proximal bare stent until the entire device is deployed.

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## INVITED COMMENTARY

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The article by Kasirajan et al highlights misalignment of the Talent Thoracic Stent Graft System (Medtronic Vascular, Santa Rosa, Calif). As they note in their article, misalignment can and does occur with all of the currently available thoracic stent graft systems. It is likely that this evaluation significantly underestimates the occurrence of this phenomenon, and it is clear that we do not have a real understanding of why this occurs in each instance.

Misalignment, as defined by a lack of alignment of the stent graft parallel to the walls of the aorta, occurs much more frequently than noted; however, confining the definition, as the authors have done, to "retroflexed" proximal stents, which could be considered severe misalignment, occurs much less frequently. There are several intriguing issues regarding the findings and several important points the authors note as well.

The incidence of this event appears to be much more frequent in the United States than in Europe, occurring in almost 2% of patients (1.7% per patient calculation) in the United States commercial sales. Even this incidence is probably under-representing the true incidence. In addition, although the authors note that this is more common to occur with larger graft sizes, without knowing the percentage of use of the larger devices, it is difficult to implicate simply increased graft size as the issue. There is no information regarding the degree of over-sizing and no information regarding patient features alone, which may be responsible for these issues. Finally, although limited sequelae have been noted in these cases, the long-term events for these patients have not been defined, and it remains to be seen how individuals with these devices will fare, and in fact, how the devices themselves will fare when deployed in a manner that is completely outside the anatomic situation for which they were designed.

Significantly, the authors have pointed out a number of tips that can be used during deployment that can help to decrease the occurrence of this problem. Although it is important for any physician deploying implantable devices to understand how the device works and how the deployment system works, it is likely more important to understand how the device and its deployment mechanism fail and how this can be avoided or managed. The tips the authors have outlined here should be heeded by those using these devices, especially in tortuous aortic anatomy. Similar understanding of deployment mechanics and the failure modes of the deployment mechanics would be helpful to understand for all endovascular grafts, and it is only through publications such as this

that these facts can be recognized, assessed, and in the end hopefully, averted.

On a final note, it is important to note that Medtronic has recognized the deficiencies related to its current deployment mechanism and has re-engineered its system to attempt to obviate these problems. Here again, clinician input and exchange are an important part of the process highlighting shortcomings of current device design and providing important feedback to device manufacturers regarding these concerns. Reports like this regarding new technologies and identification of problems and difficulties along with methods of avoiding or preventing them are an important part of the medical and surgical literature and provide much needed information that ultimately benefits patients, clinicians, and device manufacturers.