

## A-View Endotracheal Balloon Catheter

November, 2023

### Device

The A-View Endotracheal Balloon Catheter allows for inspection of the aortic arch and distal ascending aorta during transesophageal echocardiography (TEE).<sup>1</sup> According to manufacturers, this device addresses this common 'blind spot' of TEE due to air in the trachea, and is a valid method of real-time imaging, improving patient outcomes.<sup>2</sup> A saline filled balloon catheter is inserted into the trachea which enables echo conduction to enhance imaging, allowing the surgeon to see the structure of these areas, including atherosclerosis plaques, a major cause of embolic stroke.<sup>3</sup>

### Actions for Consideration

**Partner:** Identify the appropriate clinical and value analysis team members to assess with the review of this technology. Essential clinical team members may include those with specialized knowledge in stroke care and prevention, cardiology practice, and cardiology outcomes. These may include neurologists, interventional cardiologists, echocardiographers, neurointerventional radiologists, cardiovascular surgeons, interventional cardiology nurses, infection prevention, and quality management.

**Connect:** A careful review of the potential benefit of this product is helpful. This may include an internal review of current cardiology outcomes. Due to the minimal clinical studies in this category, physician data including usage, cost, and waste will help inform management of these products. Reimbursement information should be attained. Identify evidence related to specific products.

**Communicate:** When a change in utilization is recommended, ensure sharing of product education with all end users. This may include partnering with the supplier for training on new technology. A comprehensive communication plan will help ensure successful implementation. Discuss pricing, reimbursement, and develop strategies to manage use. Robust data sharing will not only enhance discussions, but may lead to actionable conversations between peers.

**HealthTrust Resources:** Access the [Clinical Knowledge Insights Library](#) to find checklists and toolkits with actionable information. Examples for this category include resources on product conversion, value analysis, and communication plans.<sup>4</sup> Network on the [HealthTrust Huddle](#), our member community that shares ideas and seeks guidance from colleagues.<sup>5</sup>

### Professional Society Statements and Clinical Practice Guidelines

The *Recommended Standards for the Performance of Transesophageal Echocardiographic Screening for Structural Heart Intervention: From the American Society of Echocardiography*, published in 2022, outlines current standards for echocardiographic imaging. This document includes a list of views that define a comprehensive TEE examination.<sup>6</sup>

### FDA Approval

The A-View Catheter has an FDA 510(k) premarket approval (K170338; found [here](#)), and is intended to be used for:

“A-View® is intended for use in conjunction with TEE investigation of the upper mediastinum in anesthetized patients. They allow visibility of the distal ascending aorta by TEE and permit the condition of the ascending aorta to be evaluated before surgery. A-View® is limited for use in adult patients.”<sup>7</sup>

## Clinical Evidence

Evidence for this device is limited. Summaries of the available studies are described below.

- A cohort study by Klomp et al. (2017) assessed the use of perioperative TEE screening using the A-View method (saline balloon; N = 1,391 patients) as compared to conventional TEE (N = 7,214) for patients in the Netherlands. The authors concluded that patients receiving the A-View method of TEE had a lower postoperative mortality, but not stroke, after multivariate and propensity score adjustments (correction for potential confounding variables). Limitations of this study included the observational study design (not-random) and the potential for uncontrolled confounding variables. One author of the study was noted to be the inventor of the technique and chief medical officer of the balloon company.<sup>8</sup>
- A technique review by Klomp et al. (2016) described the use of a saline filled balloon to assess the ‘blind spot’ of TEE and provide better visualization of the thoracic aorta and branch vessels. The authors discussed potential complications of cardiothoracic surgery and different imaging methods available to screen patients for atherosclerosis.<sup>9</sup>

## Summary

Careful review and understanding of patient need and product attributes will help determine direction and potential opportunity. Share data and evidence to engage physicians. When considering the introduction of a new product ensure physicians are included in the discussion, that evidence and pricing are shared, and appropriate support is provided from the supplier or physician peer.

## References

1. DeRoyal. A-View Endotracheal balloon catheter. [https://www.derooyal.com/docs/default-source/a-view-product-studies/ifu/sf-training---marketing-pm--quick-basics.pdf?sfvrsn=e6895a98\\_12](https://www.derooyal.com/docs/default-source/a-view-product-studies/ifu/sf-training---marketing-pm--quick-basics.pdf?sfvrsn=e6895a98_12). Published 2021. Accessed October 26, 2023.
2. DeRoyal. A-View. <https://www.derooyal.com/products/surgical/a-view>. Published 2023. Accessed October 26, 2023.
3. DeRoyal. Vascular TEE Views. [https://www.derooyal.com/docs/default-source/a-view-product-studies/literature/0-2545-vascular-tee-guideline-a-view.pdf?sfvrsn=42041de2\\_10](https://www.derooyal.com/docs/default-source/a-view-product-studies/literature/0-2545-vascular-tee-guideline-a-view.pdf?sfvrsn=42041de2_10). Published 2022. Accessed October 26, 2023.
4. HealthTrust Performance Group. Clinical Knowledge Insights. <http://www.hpginsights.com/>. Published 2023. Accessed September 25, 2023.
5. HealthTrust Performance Group. HealthTrust Huddle. <https://huddle.healthtrustpg.com/forum/>. Published 2023. Accessed September 25, 2023.
6. Hahn RT, Saric M, Faletta FF, et al. Recommended Standards for the Performance of Transesophageal Echocardiographic Screening for Structural Heart Intervention: From the American Society of Echocardiography. *J Am Soc Echocardiogr*. 2022;35(1):1-76.
7. U.S. Food & Drug Administration. 510(k) Premarket Notification: A-View. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K170338>. Published 2023. Accessed October 26, 2023.
8. Jansen Klomp WW, Moons CGM, Nierich AP, et al. Impact of Modified Transesophageal Echocardiography on Mortality and Stroke after Cardiac Surgery: A Large Cohort Study. *Int J Vasc Med*. 2017;2017:1857069.
9. Jansen Klomp WW, Brandon Bravo Bruinsma GJ, van 't Hof AW, Grandjean JG, Nierich AP. Imaging Techniques for Diagnosis of Thoracic Aortic Atherosclerosis. *Int J Vasc Med*. 2016;2016:4726094.