

# **Balloon Aortic Valvuloplasty Market Size and Forecast (2021 - 2031), Global and Regional Share, Trend, and Growth Opportunity Analysis Report Coverage: By Product Type (Non-Compliant Balloons and Semi-Compliant Balloons) and Geography (North America, Europe, Asia Pacific, Middle East & Africa, and South & Central America)**

<https://marketpublishers.com/r/B5A285A9ED9CEN.html>

Date: June 2024

Pages: 160

Price: US\$ 5,190.00 (Single User License)

ID: B5A285A9ED9CEN

## **Abstracts**

The balloon aortic valvuloplasty market size is expected to grow from US\$ 125.08 million in 2023 to US\$ 190.27 million by 2031; it is projected to register a CAGR of 5.4% during 2023-2031. The rising prevalence of aortic valve stenosis and increasing demand for minimally invasive procedures are noteworthy factors contributing to the expansion of the balloon aortic valvuloplasty market size. However, the high cost of procedures hinders the balloon aortic valvuloplasty market growth.

TAVR was originally considered only for patients with severe aortic stenosis who were considered inoperable or at very high risk. However, continuous technological evolution in valve technology and the results of randomized trials have expanded its usage to younger and lower-risk patients, making it a mainstream treatment for aortic valve disease. With developments in valve production technologies, bioprosthetic heart valves are becoming more popular and applicable to younger and lower-risk patients. With its minimally invasive feature, a majority of valve replacements will soon be via TAVR. New-generation transcatheter heart valves have substantially improved procedural efficacy, safety, and patient outcomes, making TAVR an appealing option for different patient risk groups.

Predicting the performance of the heart valve upon implantation is critically important for

a successful TAVR. It is desirable to mechanically assess selected heart valves before implantation to ensure proper valve function with minimal complications after implantation. A potential practical and effective solution for applying engineering analysis to the mechanical assessment of heart valves is incorporating deep learning (DL)-based systems to advance and simplify the computational biomechanical analyses relevant to TAVR. In recent years, immense developments in DL techniques have led to state-of-the-art performances in many computer vision tasks, including image classification, image segmentation, and object detection. DL has been extensively investigated for various cardiac imaging applications, including diagnostic, prognostic, risk stratification, and therapeutic/surgical treatment planning. Numerous studies have investigated DL approaches for assessing TAVR outcomes to predict postoperative complications and prosthetic valve defects.

Through continuous research and development, the future of TAVR promises breakthrough possibilities, further strengthening its place as a transformative therapy in cardiovascular medicine. Currently, only the Edwards SAPIEN 3 Ultra, Medtronic EVOLUT FX, and Abbott Navitor valves have been approved by the FDA. Although most of the clinical experience with TAVR is linked to the Edwards and Medtronic valve systems, the potential transcatheter heart valves lineup extends beyond these leaders, with as many as five to ten new TAVR valves in the development phase. The future of TAVR appears bright, with indications growing, procedural volumes soaring, and an increasing number of clinical sites offering the procedure, although long-term durability remains a key concern. The leaflets of currently available valves are derived from porcine or bovine pericardial tissue. New valve platforms incorporating creative leaflet materials and other design innovations are being developed to increase long-term durability. Some new trials promise to offer crucial guidance for TAVR operators seeking to offer long-term solutions. The SMART (i.e., Small Annuli Randomized to Evolut or SAPIEN) trial is the first randomized industry-sponsored (Medtronic) head-to-head comparison of the two most commonly used TAVR devices: SAPIEN 3 and Evolut in small anatomies. The trial was conducted at 83 international sites in North America, Europe, and the Middle East & Africa. The trial enrolled 716 participants with a small aortic annulus (aortic annulus area of 430 mm<sup>2</sup> or less based on multi-detector computed tomography) and symptomatic severe native aortic stenosis. In April 2024, the American College of Cardiology announced that findings from the SMART trial demonstrated that patients with a small aortic annulus who underwent TAVR with Evolut valve had similar clinical outcomes and superior valve performance at one year compared with patients who underwent TAVR with SAPIEN 3 valve. Researchers said the results are encouraging in terms of the clinical outcomes of both valve types. Researchers will continue to track outcomes over the next five years. Thus, research

and development activities focused on improving TAVI procedures are likely to bring in new trends in the balloon aortic valvuloplasty market.

### Product Type -Based Insights

Based on product type, the balloon aortic valvuloplasty market is segmented into non compliant balloons and semi compliant balloons. The non compliant balloons segment held a larger balloon aortic valvuloplasty market share in 2023 and is expected to register a higher CAGR in the market during 2023–2031.

National Echo Database of Australia and the Institute of Health Economics are among the primary and secondary sources referred to while preparing the balloon aortic valvuloplasty market report.

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