Certain information and statistics set out in this section and elsewhere in this prospectus relating to the industry in which we operate are derived from the Frost & Sullivan Report prepared by Frost & Sullivan, an independent industry consultant which was commissioned by us. The information extracted from the Frost & Sullivan Report should not be considered as a basis for investments in the Offer Shares or as an opinion of Frost & Sullivan as to the value of any securities or the advisability of investing in our Company. We believe that the sources of such information and statistics are appropriate for such information and statistics and have taken reasonable care in extracting and reproducing such information and statistics. We have no reason to believe that such information and statistics are false or misleading or that any fact has been omitted that would render such information and statistics false or misleading in any material respect. Our Directors have further confirmed, after making reasonable enquiries and exercising reasonable care, that there is no adverse change in the market information since the date of publication of the Frost & Sullivan Report or any of the other reports which may qualify, contradict or have an impact on the information in this section. No independent verification has been carried out on such information and statistics by us, the Joint Sponsors, the Joint Global Coordinators, the Joint Bookrunners, the Joint Lead Managers, the Underwriters or any other parties (other than Frost & Sullivan) involved in the Global Offering or their respective directors, officers, employees, advisers, or agents, and no representation is given as to the accuracy or completeness of such information and statistics. Accordingly, you should not place undue reliance on such information and statistics. Unless and except for otherwise specified, the market and industry information and data presented in this "Industry Overview" section is derived from the Frost & Sullivan Report.[1]

OVERVIEW OF VALVULAR HEART DISEASE

Classification of Heart Diseases

Heart disease, often used interchangeably with the term "cardiovascular disease", is a general term that describes heart abnormalities, including structural heart diseases, coronary heart disease, arrhythmia and heart failure. In 2019, heart disease caused 18.4 million deaths globally, representing 32.7% of global deaths in the same year. Structural heart disease is a new concept proposed in the

1 In connection with the Global Offering, we commissioned Frost & Sullivan, an Independent Third Party, to prepare a report on China's transcatheter valve therapeutic procedural medical device markets. We have agreed to pay a total of RMB1 million in fees for the preparation of the Frost & Sullivan Report. Frost & Sullivan is a market research and consulting company founded in 1961 that provides market research on a variety of industries including healthcare.

In preparing the report, Frost & Sullivan conducted primary and secondary research to collect data and deliver conclusions. In detail, Frost & Sullivan collected and reviewed publicly available data such as government-derived information, annual reports and industry association statistics, as well as market data collected by conducting interviews with key industry experts and leading industry participants. Primary research includes in-depth, telephone and face-to-face discussion with key industry experts and leading industry participants. Secondary research includes (i) government-derived information, such as National Health and Family Planning Commission, US Food and Drug Administration, National Medical Products Administration and etc. (ii) Frost & Sullivan in-house research (iii) industry reports (iv) industry literature and (v) annual reports of listed companies. In particular, according to Frost & Sullivan, the number of eligible patients and relevant analysis are based on epidemiological and clinical studies and literature research, which has taken into consideration the learning curve of physicians and the qualifications and capabilities of hospitals that can perform TAVI procedures.

The market projections in the commissioned report are based on the following key assumptions:

- the overall social, economic and political environment in the PRC is expected to remain stable during the forecast period;
- China's economic and industrial development is likely to maintain steady growth over the next decade;
- key industry drivers, such as accelerated aging population, growing demands from healthcare institutions, the increasing prevalence of chronic diseases, and continuous technology innovation are likely to drive the growth of China's medical device market during the forecast period; and
- no extreme force majeure or industry regulation will dramatically or fundamentally affect the market.

Except as otherwise noted, all data and forecasts in this section come from the Frost & Sullivan Report. Our Directors confirm that, to the best of their knowledge, after taking reasonable care, there has been no adverse change in market information since the date of the Frost & Sullivan Report which may qualify, contradict or impact the information disclosed in this section.

field of cardiovascular disease in recent years, which, in a broad sense, refers to any abnormality of the heart structure and any disease related to the heart and large blood vessel structure other than the primary cardiac disease and circulatory disease. The narrow structural heart disease refers to the pathophysiological changes of the heart caused by anatomical abnormality changes in the heart structure, including (i) congenital heart disease; (ii) valvular heart disease; (iii) cardiomyopathy; and (iv) ventricular septal perforation, ventricular aneurysm, scar myocardial, etc.

Valvular heart disease is a structural heart disease involving the damage to or defect in one of the four heart valves, namely aortic, tricuspid, mitral and pulmonary valves. With valvular heart disease, the valves become too narrow and hardened to open fully (stenosis), or are unable to close completely (regurgitation). In 2019, approximately 213.2 million patients suffered from valvular heart disease globally, which caused 2.6 million deaths. Aortic stenosis and mitral regurgitation are the most common types of valvular heart diseases by prevalence, representing 9.2% and 45.4% respectively of global valvular heart disease patients in 2019. Tricuspid valve disease, including tricuspid stenosis and tricuspid regurgitation, is another common type of valvular heart disease.

Valvular heart disease is a common structural heart disease in China. In 2019, there were 36.3 million patients suffering from valvular heart disease in China, which is expected to increase to 40.2 million in 2025. In particular, aortic stenosis, mitral regurgitation and tricuspid regurgitation represent 11.8%, 29.2% and 25.1% of valvular heart disease patients in China in 2019, respectively. Valvular heart disease is increasingly prevalent among the population aged over 65 years old in China, primarily because of the prevalence of rheumatic fever and degenerative changes, along with other factors including the improvement of living standards, aging population and life-time dilation. The population over 65 years old in China is 176.0 million in 2019, representing 12.6% of the total population, and is expected to reach 309.3 million in 2030, representing 21.5% of the total population. With increasing health consciousness, the improvement of patient affordability, the expansion of governmental medical reimbursement coverage and the improvement of living standards, the visiting rate and the diagnostic rate of valvular heart disease are expected to significantly grow in the near future.

Aortic Valve Disease

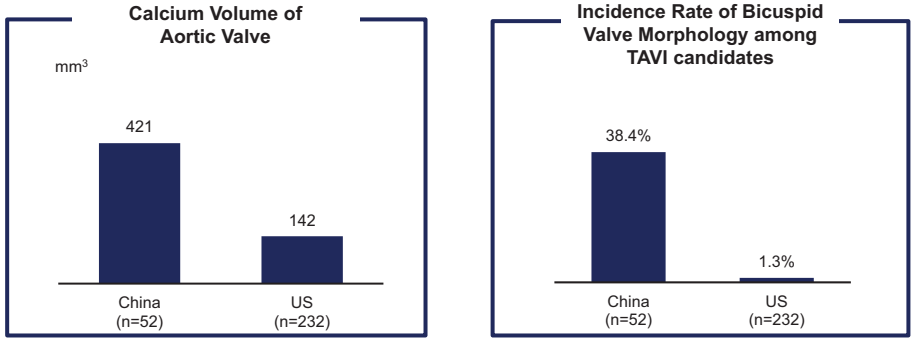
Aortic Stenosis

Overview of Aortic Stenosis

Aortic stenosis ("**AS**") is the narrowing of the aortic valve, obstructing the blood flow from the left ventricle to the ascending aorta during systole. Causes of AS mainly include congenital bicuspid aortic valve, idiopathic degenerative sclerosis with calcification and rheumatic fever. Unless an aortic valve replacement procedure is performed promptly, the mortality rate for patients that progressed to the symptomatic stage of AS within two years following diagnosis is higher than 50%.

Compared with AS patients in the U.S., AS patients in China generally have a higher calcium volume and high percentage of bicuspid aortic valve morphology. Such features generally require certain special designs in TAVI products, such as special frame design with strong bottom radial force to push aside the valve leaflets with severe calcification. The following chart illustrates the comparison between

China and the U.S in respect of calcium volume and the bicuspid valve morphology incidence rates based on 52 sampled patients in China and 232 sampled patients in the U.S.



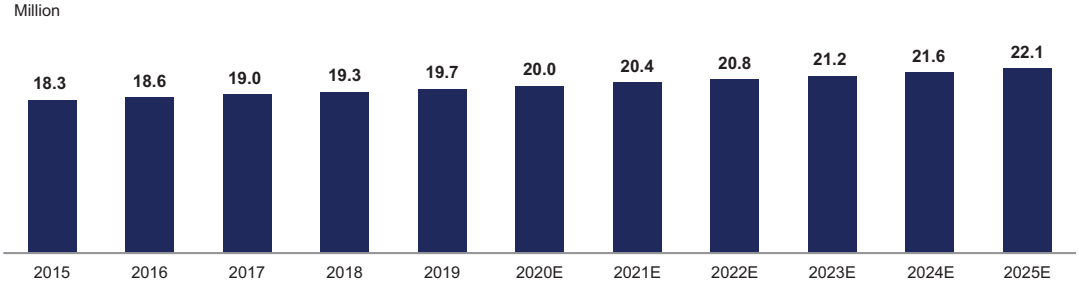
Source: Frost & Sullivan Report

Prevalence of Aortic Stenosis

Generally speaking, the prevalence of AS is associated with aging. Globally, 2% to 7% of adults over 65 years old suffer from AS. The number of global AS patients increased from 18.3 million in 2015 to 19.7 million in 2019, and is expected to reach 22.1 million in 2025. The following chart sets forth the historical and forecasted prevalence of AS globally.

Global Prevalence of Aortic Stenosis[1], 2015-2025E

Period	CAGR
2015-2019	1.8%
2019-2025E	2.0%



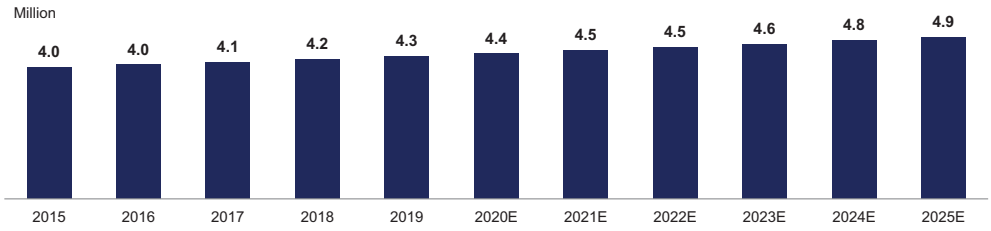
1. Unless otherwise specified, aortic stenosis includes congenital aortic stenosis, rheumatic aortic stenosis and degenerative aortic stenosis, among others.

Source: Frost & Sullivan Report

In China, the number of AS patients increased from 4.0 million in 2015 to 4.3 million in 2019, and is expected to reach 4.9 million in 2025. The following chart sets forth the historical and forecasted prevalence of AS in China.

Prevalence of Aortic Stenosis in China, 2015-2025E

Period	CAGR
2015-2019	2.0%
2019-2025E	2.2%



Source: Frost & Sullivan Report

Aortic Regurgitation

Overview of Aortic Regurgitation

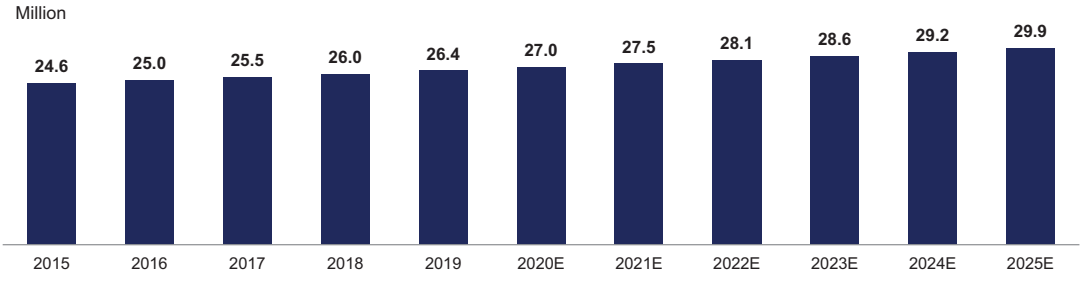
Aortic regurgitation ("**AR**") is the incompetency of the aortic valve of the heart that causes blood to flow in the reverse direction during ventricular diastole, from the aorta into the left ventricle. Causes of AR include valvular degeneration, rheumatic disease, endocarditis and aortic root dilation. Typically many AS patients are also accompanied with AR symptoms and there are very few pure-AR patients. Current treatment methods for AR primarily include SAVR and valve repair, and, to a lesser extent, certain TAVI products.

Prevalence of Aortic Regurgitation

Global AR patient population gradually increased from 24.6 million in 2015 to 26.4 million in 2019, and is expected to reach 29.9 million in 2025. The following chart sets forth the historical and forecasted prevalence of AR globally.

Global Prevalence of Aortic Regurgitation, 2015-2025E

Period	CAGR
2015-2019	1.9%
2019-2025E	2.1%

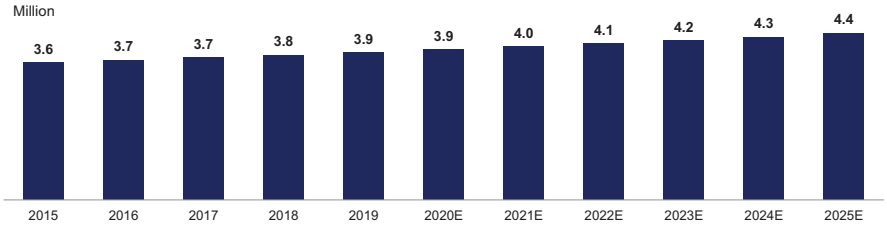


Source: Frost & Sullivan Report

In China, the number of AR patients increased from 3.6 million in 2015 to 3.9 million in 2019, and is expected to reach 4.4 million in 2025. The following chart sets forth the historical and forecasted prevalence of AR in China.

Prevalence of Aortic Regurgitation in China, 2015-2025E

Period	CAGR
2015-2019	1.8%
2019-2025E	2.1%



Source: Frost & Sullivan Report

Mitral Valve Disease

Mitral valve disease mainly consists of mitral regurgitation ("**MR**") and mitral stenosis. Major causes of mitral valve disease include congenital disease, rheumatic fever and aging. In 2019, 113.0 million patients globally were affected by mitral valve diseases, which is expected to reach 127.1 million in 2025. In 2019, there were 16.4 million patients in China suffering from mitral valve diseases, which are expected to reach 18.8 million in 2025.

Mitral Regurgitation

Overview of Mitral Regurgitation

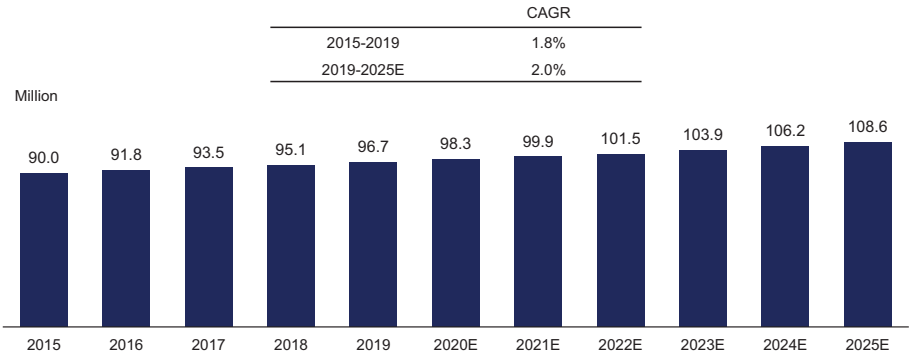
MR refers to the mitral valve's inability to close completely, causing blood to flow from the left ventricle into the left atrium during ventricular systole. Generally, the prevalence of MR is associated with aging. Among the population over 65 years old, over 15% and 25% suffer from MR in western countries[(1)] and China respectively**.** Studies have indicated that patients diagnosed with severe MR who do not undergo surgery generally have mortality rates of 20% after one year following diagnosis and 50% after five years following diagnosis.

(1) "Western countries" refer to western developed countries that have a high TAVI penetration rate, primarily including the United States and developed countries in Europe, such as the United Kingdom and Germany

Prevalence of MR

Globally, the population of MR patients increased from 90.0 million in 2015 to 96.7 million in 2019, and is expected to reach 108.6 million in 2025. The following chart sets forth the historical and forecasted prevalence of MR globally.

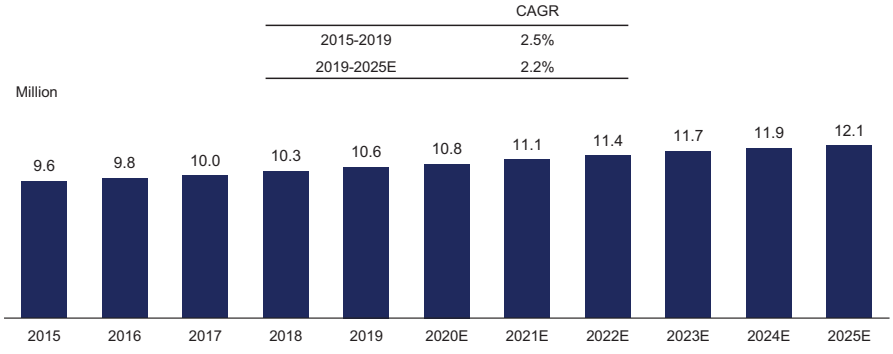
Global Prevalence of Mitral Regurgitation, 2015-2025E



Source: Frost & Sullivan Report

In China, the population of MR patients increased from 9.6 million in 2015 to 10.6 million in 2019, and is expected to reach 12.1 million in 2025. The following chart sets forth the historical and forecasted prevalence of MR in China.

Prevalence of Mitral Regurgitation in China, 2015-2025E



Source: Frost & Sullivan Report

Tricuspid Valve Disease

Tricuspid valve disease mainly consists of tricuspid regurgitation ("**TR**") and tricuspid stenosis. TR is the inability of the tricuspid valve to close completely, causing blood to flow from the right ventricle to the right atrium during systole. The prevalence of TR globally had reached 49.6 million in 2019, with a CAGR of 2.1% from 2015 to 2019, and is estimated to reach 55.9 million patients in 2025. The prevalence of TR in China had reached 9.1 million in 2019 and is estimated to grow to 9.9 million in 2025. However, due to the difficulties in developing effective treatments and challenges in performing surgeries for tricuspid valve disease, as of the Latest Practicable Date, there were only three commercialized TTV repair products in Europe, none of which had been approved in the U.S. or China.

Treatment for Valvular Heart Diseases

Overview

Valvular heart diseases may be treated by pharmacological approach or surgical procedures. As of the Latest Practicable Date, surgical procedures for valvular heart diseases were categorized into (i) traditional open-chest surgery, (ii) minimally invasive valve surgery, and (iii) transcatheter valve therapy ("**TVT**"), such as TAVI, TMV repair, TMV replacement and TTVR procedures. In the future, TVTs are expected to be key directions of the development of treatments for valvular heart diseases in light of their advantages of lower surgical risks, minor trauma, shorter postoperative hospitalization time and less incidences of postoperative complications.

Treatment for Aortic Valve Diseases

Overview

AS can be treated by surgical procedures. In recent years, TAVI has emerged to be one of the treatment methods for severe aortic stenosis patients, especially for those who are inoperable by traditional surgical procedure, namely SAVR. According to the guideline on valvular heart disease released by the American College of Cardiology and American Heart Association ("**ACC/AHA Guideline**") in 2014, SAVR is recommended for patients with low or intermediate surgical risk (patients with an STS Score below 8), and TAVI is a reasonable alternative to SAVR for patients with high surgical risk (patients with an STS Score above 8). In the updated version of the ACC/AHA Guideline in 2017, the application of TAVI was expanded to patients with intermediate surgical risk (patients with an STS Score between 4 to 8). In August 2019, FDA approved the performing of TAVI procedures on patients with low to intermediate surgical risk. It is expected that regulators in China will follow a similar trend and TAVI will be approved for patients with low to intermediate surgical risks in China in the future. Further, there are also a number of AS patients that can not be treated by SAVR. In 2019, these SAVR inoperable patients amounted to approximately 1.1 million and approximately 230,100 globally and in China, respectively.

Comparison between SAVR and TAVI

For years, SAVR was the standard treatment for severe AS patients. During SAVR procedure, an incision is made in the chest to access the heart and the heart is stopped for removing and replacing the dysfunctional aortic valve with a new valve, which is relatively more invasive. TAVI is a globally advanced TVT where a prosthetic aortic valve is implanted using a guide tube called a catheter. Usually, the catheter is inserted into the artery in patient's groin (transfemoral approach) or through a small incision in the patient's chest (transapical or transaortic approach). In general, the transfemoral approach is less invasive, which is accessed through the femoral artery without an incision but with a needle catheter and long wires allowing access to the dysfunctional valve. As a result, the transfemoral approach is the most recommended method for clinical practice in China. The transapical approach involves accessing the chest into the apex of the patient's heart and the transaortic approach requires cutting through a portion of the breastbone or through a small incision between the ribs on the right side of the sternum.

Generally, compared with SAVR procedures, TAVI procedures provide a less invasive treatment solution. TAVI procedures typically take one to two hours to perform, whereas SAVR procedures

typically take three to six hours to perform. In addition, TAVI adopts an interventional operation method, causing less surgical risks, minor trauma and therefore has shorter hospitalization time and postoperative recovery period. The charts below set forth a comparison between TAVI procedures and SAVR procedures in China.

○ Low ● High		SAVR	TAVI
Surgery	Anesthesia	General	Local/General
	Complexity	●	◔
	Risk	◕	◑
	Time	● ~4-5 hours	◑ ~2-3 hours
Results	Wounds	●	◑
	Complications	◕ Infection, stroke, blood clots and irregular heartbeats, etc.	◔ Conduction block, stroke and PVL, etc.
	in-hospital time	2~3 weeks	1~2 week
Cost	Valve	○ ~RMB10,000 to 30,000	◕ ~RMB200,000 to 300,000
	Total (Including Valve and Operation)	◑ ~RMB60,000 to 80,000	● ~RMB300,000

Source: Frost & Sullivan Report

Compared with SAVR procedures, TAVI procedures generally have higher requirements for the qualifications of hospitals and equipment of the facilities. According to the Consensus of Chinese Experts on Transcatheter Aortic Valve Replacement (經導管主動脈瓣置換術中國專家共識) and Expert Consensus on Clinical Pathway of Transcatheter Aortic Valve Replacement in China (中國經導管主動脈瓣置換術臨床路徑專家共識), TAVI procedures are supposed to be performed at a hybrid operation room or a modified cardiac catheterization room, which should be equipped with a digital subtraction angiography system, anesthesia equipment, echocardiography equipment and extracorporeal circulation, among others. Hospitals that can perform over 400 PCIs per year are considered eligible hospitals for TAVI procedures. In addition, TAVI procedures shall involve multiple-disciplinary cardiac teams consisting of two to three interventional physicians each with experience of over 200 interventional operations per year, one to two cardiac surgeons, one radiologist, one anesthesiologist, one echocardiography doctor and two to three nurses. Physicians also need to at least perform 20-30 TAVI procedures as learning curve to master the core skills in a TAVI procedure. As such, in 2019, there were 604 eligible hospitals for TAVI procedures in China but only 156 hospitals performed TAVI procedures.

Treatment for Mitral Regurgitation

For patients with severe MR, the standard treatment is mitral valve replacement or repair under extracorporeal circulation through open-chest surgery. TMV repair and TMV replacement have emerged as two possible alternative therapeutic options for the treatment of severe MR in patients with prohibitive or high surgical risks. Most of the current TMV repair or replacement technologies rely on the placement and fixation in the native mitral annulus and left ventricle, which is likely to result in complications such as causing obstruction of the LVOT, impairing function of the left ventricle and leading to device embolization.

Treatments for mitral valve disease are subject to the following inherent biomechanical challenges.

- *Complexity.* The cause of mitral valve disease often involves a combination of an ineffective valve, other cardiovascular failure or cardiovascular damages. The treatment of mitral valve disease is therefore much more complicated.
- *Position and structure.* The position (between the left atrium and left ventricle) and the annulus of the mitral valve increase the difficulty of precisely positioning the artificial valve, which sets higher requirements on the design of the delivery system.
- *Stent.* The large size of the mitral annulus may require a larger stent to be implanted in a TMV repair/replacement procedure. However, such a large stent may have an adverse impact, such as obstruction of the left ventricular outflow and thrombosis, and therefore, requires better designs.
- *Saddle-shaped.* Mitral annulus is saddle-shaped, which added challenges in device sizing and positioning, and as a result may lead to higher risks of complications during or after the TMV repair/replacement procedure.
- *Prone to structural damage.* Compared to the aortic valve, the mitral valve is more prone to structural damage as it is under higher left ventricular systolic pressure, which requires higher durability.

To date, there are only seven commercialized TMV repair or replacement products globally, with only one being approved in China. There are also several TMV repair or replacement products under development to overcome these difficulties. New therapies such as using a supra-annular, atrial-only fixation technology to preserve the critical cardiac structure within the left ventricle are under development to provide more solutions for patients with mitral valve diseases.

Treatment for Tricuspid Valve Disease

Valve repair or replacement is indicated when TR is due to primary valve abnormalities or when annuloplasty is not technically feasible. However, due to the difficulties in developing effective treatments and challenges in performing surgeries for tricuspid valve disease, to date there are only three commercialized TTV repair products in Europe, none of which had been approved in the U.S. or China.

The mitral valve and the tricuspid valve share certain structural similarities. The geometric and characteristics changes of the right ventricle can directly affect the tricuspid regurgitation, whereas mitral regurgitation is largely affected by the geometric and characteristic of the left ventricle. As a result, studies have indicated the possibility to transform certain TMV technologies in the treating of tricuspid valve disease.

TAVI MARKET

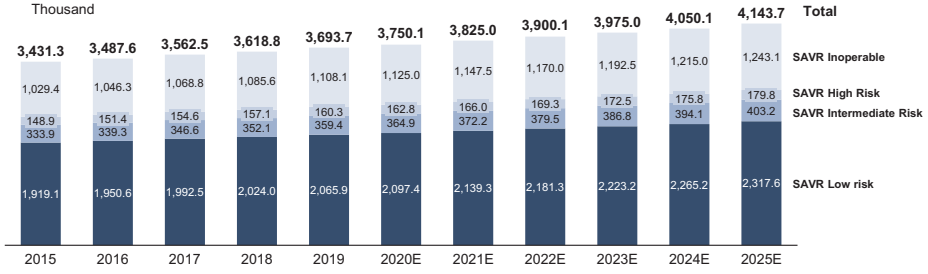
Global Market

Eligible patients for TAVI procedures include SAVR inoperable patients, SAVR high-risk patients, as well as SAVR intermediate-risk and low-risk patients, which were included in the

indications of TAVI by the FDA in August 2019. Globally, the number of eligible patients for TAVI procedures increased from approximately 3.4 million in 2015 to approximately 3.7 million in 2019, and is expected to reach 4.1 million in 2025. The table below sets forth the historical and forecasted number of eligible patients for TAVI procedure globally.

Global Eligible Patients for TAVI Procedures, 2015-2025E

Period	CAGR
2015-2019	1.9%
2019-2025E	1.9%

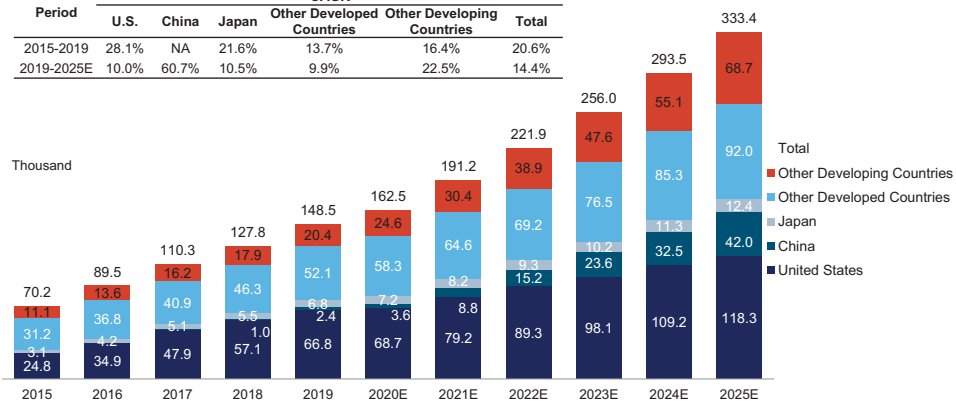


Source: Frost & Sullivan Report

In 2019, over 80.0% of the global TAVI procedures were completed in developed countries, including the United States and Japan, with nearly one eligible patient in every five on average having received TAVI treatment in the same year. In contrast, the penetration rate in China was only 0.3% in 2019. Driven by the large patient pool, the increasing acceptance of TAVI procedure by patients, the increasing number of eligible hospitals and qualified practitioners, the expected favorable medical insurance reimbursement inclusion, and the aging population, it is expected that China will experience the highest growth rate in the future, representing a CAGR of 60.7% from 2019 to 2025. In addition, other developing countries excluding China are also expected to experience rapid growth in the future, increasing at a CAGR of 22.5% from 2019 to 2025. The following chart sets forth the historical and forecasted number of global TAVI procedures by regions.

Number of Global TAVI Procedures, 2015-2025E

Period	CAGR					
	U.S.	China	Japan	Other Developed Countries	Other Developing Countries	Total
2015-2019	28.1%	NA	21.6%	13.7%	16.4%	20.6%
2019-2025E	10.0%	60.7%	10.5%	9.9%	22.5%	14.4%



Source: Frost & Sullivan Report

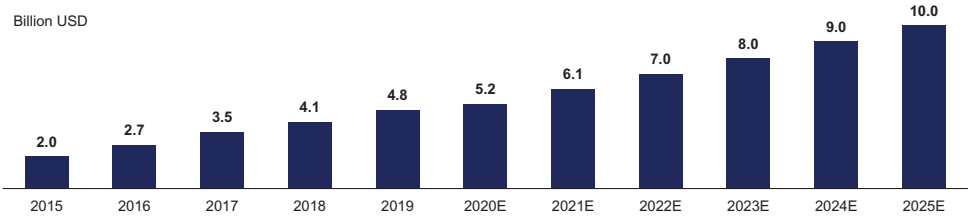
Market Size

The global TAVI market has experienced rapid growth, growing from US$2.0 billion in 2015 to US$4.8 billion (or RMB32.3 billion) in 2019. It is expected that it will continue its growth and reach

US$10.0 billion (or RMB67.3 billion) in 2025, doubling the market size in 2019. The following chart sets forth the historical and forecasted growth of the global TAVI market.

Global TAVI Market Size, 2015-2025E

Period	CAGR
2015-2019	25.1%
2019-2025E	12.9%



Source: Frost & Sullivan Report

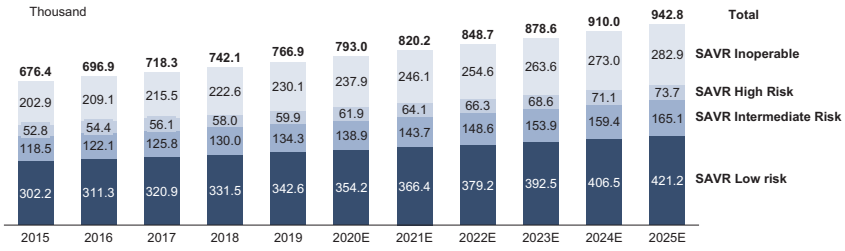
China Market

Eligible Patients for TAVI Procedures

Currently, TAVI is only approved for aortic stenosis patients who are not suitable for surgeries and patients with high surgical risks in China. In 2019, there were approximately 290,000 aortic stenosis patients that fall within the current addressable patient group for TAVI procedures in China. In contrast, in recent years, FDA has expanded the indications of TAVI to include aortic stenosis patients with low to intermediate surgical risks. According to Frost & Sullivan, it is expected that TAVI will also be approved for aortic stenosis patients with low to intermediate surgical risks in China in the future. Accordingly, all of these patients are considered eligible patients for TAVI procedures. The number of eligible patients for TAVI procedures in China increased from approximately 676,400 in 2015 to approximately 766,900 in 2019 and is expected to reach approximately 942,800 in 2025. The following chart sets forth the historical and forecasted number of eligible patients for TAVI procedures in China.

China Total Eligible Patients for TAVI Procedures, 2015-2025E

Period	CAGR
2015-2019	3.2%
2019-2025E	3.5%



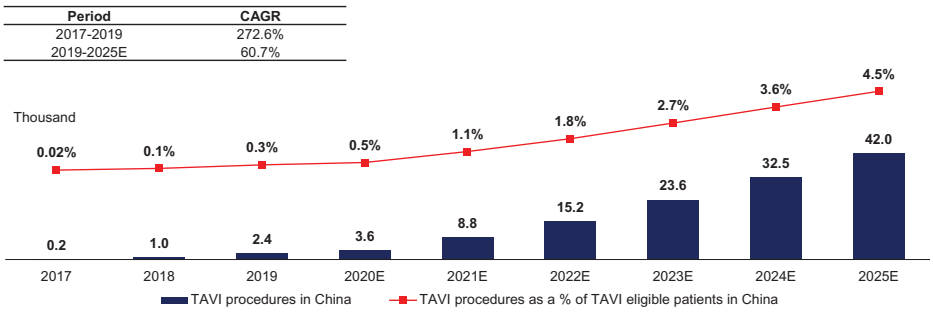
Source: Frost & Sullivan Report

Number of TAVI procedures and Penetration Rate

In 2019, there were only approximately 2,400 TAVI procedures performed in China, treating only 0.3% of the eligible patient group. With the growing acceptance of TAVI procedures, an increasing number of eligible hospitals and the expected inclusion of SAVR intermediate- and low-risk patients in indications, it is expected that 4.5% of the eligible patients for TAVI procedures in

China will benefit from the approximately 42,000 TAVI procedures in 2025. The following chart sets forth the historical and forecasted penetration rate and the growth of TAVI procedures in China.

TAVI Procedures[1] and Penetration Rate in China, 2017-2025E



Note:

1. The number of TAVI procedures only includes surgeries with commercial TAVI products

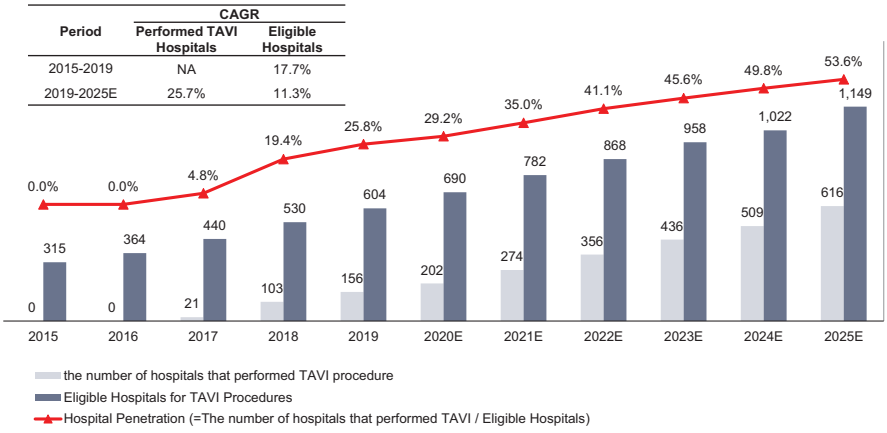
Source: Frost & Sullivan Report

Eligible Hospitals to Perform TAVI Procedures in China

Due to the complexity of TAVI procedures, hospitals that can perform over 400 PCIs per year are considered eligible hospitals for TAVI procedure. In 2019, there were 604 eligible hospitals for TAVI procedures in China but only 156 hospitals performed TAVI procedures. The TAVI market in China is highly concentrated with respect to hospitals with the Top 20 TAVI Hospitals playing an important role in the market. It is expected that in 2020, 73.5% of the TAVI in China will be performed at the Top 20 TAVI Hospitals in 2020.

The future growth of TAVI market in China will also be driven by the expansion of eligible hospital group for TAVI procedures and the higher hospital penetration rate. With the development in physician training and hospital infrastructure and increasing availability of clinical resources to support the multi-disciplinary nature of TAVI procedure, it is expected that in 2025, there will be 1,149 eligible hospitals for TAVI procedures in China. Market players that can provide customized assistance to these hospitals in performing their first TAVI procedures are expected to benefit the most from these growth opportunities. The following chart sets forth the historical and forecasted eligible hospitals for TAVI procedures and the number of hospitals that have performed or is expected to perform TAVI procedures in China.

Eligible TAVI Hospitals and Hospital Penetration Rate in China, 2015-2025E

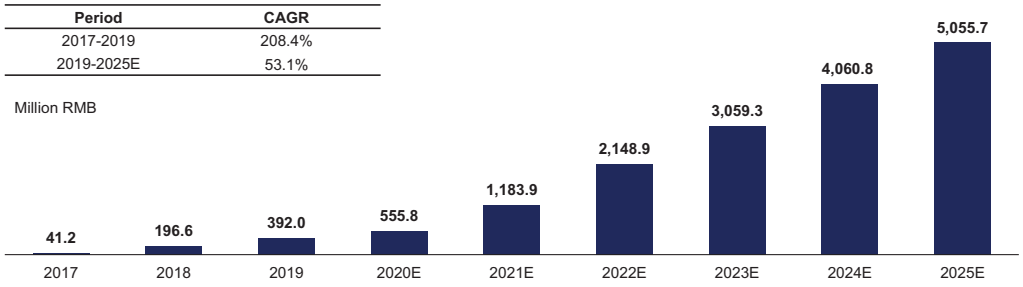


Source: Frost & Sullivan Report

Market Size and Growth Drivers

In 2019, the market size of the TAVI market in China was RMB392.0 million. It is expected that the TAVI market will experience rapid growth at a CAGR of 53.1%, reaching RMB5,055.7 million in 2025. The following chart sets forth the historical and forecasted growth of China's TAVI market.

China's TAVI Market Size, 2017-2025E



Source: Frost & Sullivan Report

The future growth of China's TAVI market will be primarily driven by the following factors.

- *Aging population.* With the increasing life expectancy, China has entered an aging society. In 2019, the population over 65 years old is 176.0 million in China, representing 12.6% of the total population, which is expected to reach 309.3 million, representing 21.5% of the total population in 2030. As valvular heart diseases, in particular AS, are usually associated with aging population, it is expected that aging population will drive the future growth of China's TAVI market.

- *Clinical advantage of TAVI.* Compared with the traditional SAVR method, studies have indicated that TAVI will have a lower mortality rate, and reduced risks of stroke. As TAVI is less invasive, patients generally will experience minor trauma and shorter postoperative recovery. In general, the choice between TAVI and SAVR will involve making trade-offs between multiple treatment attributes, including invasiveness, speed of recovery, mortality rates and risks of postoperative complications. With the increasing availability of trial data and study results, Chinese patients and physicians will gradually increase their preference to TAVI procedures.

- *Increasing number of qualified TAVI practitioners and eligible hospitals.* As a relatively new technology, TAVI imposes high requirements on surgical equipment, personnel configuration and technical operation. In May 2020, The updated Consensus of Chinese Experts on Transcatheter Aortic Valve Replacement (經導管主動脈瓣置換術中國專家共識) (the "**Consensus**") was released. The Consensus set out the technical training and physician cultivation. Further, TAVI products that have gradually adopted technologies such as the motorized handle can shorten the learning curve of physicians. In addition, it is expected that the number of eligible hospitals for TAVI procedures will increase to 1,149 in 2025, almost doubling the number in 2019, which will also drive the growth of China's TAVI market.

- *Application expansion on patients with low-to-intermediate surgical risk*. In August 2019, FDA approved the performing of TAVI procedures on patients with low to intermediate surgical risk. It is expected that regulators in China will follow a similar trend and TAVI will be approved for patients with low to intermediate surgical risks in China in the future, which will drive the future growth of China's TAVI market.

- *Favorable Policy Environment.* Guidelines of Plan for Development of the Pharmaceutical Industry (醫藥工業發展規劃指南) was issued to encourage the research and development and commercialization of innovative medical devices. Moreover, an expanded national reimbursement list for innovative medical devices was planned to be implemented according to the Health and Wellness Plan in Thirteenth Five-year ("十三五"衛生與健康規劃). Such favorable government policies may also sustain the further development of the TAVI market.

Future trends

It is expected that China's TAVI market will experience the following trends.

- *Significant increase in penetration rate.* Given the clinical advantages of TAVI products and the availability of clinical trial data, the social recognition and acceptance of TAVI have already gradually increased among hospitals and patients, which will also improve the market dynamic from the supply side. A portion of SAVR or other cardiovascular surgeries is also expected to turn into TAVI procedures in the future.

- *Technology upgrade to reduce risks of TAVI complications.* Common TAVI complications, such as stroke, PVL and arrhythmia, can lead to increased postoperative mortality and hospital re-admission. To tackle this problem, TAVI products have adopted some technology upgrades, such as better skirt design. It is expected that such technology upgrades will significantly help lower the risk of TAVI complications. Market players are also developing engineering miniaturization or ingenious ways of the delivery system. In addition, in line with market trends in the U.S and Europe, it is expected TAVI companies need to provide more in-sale services, including product unpacking and assembly and provision of assistance during the TAVI procedure, to familiarize physicians with these technology upgrades.

- *Affordability.* Companies with advanced technology, scaled-up production capacity and cost-effective research and development platform are expected to launch more affordable products in the future to better address unmet needs in the treatment of aortic valve disease patients.

- *Products tailored to Chinese patients.* Compared with patients in the U.S., patients in China with severe AS have higher degrees of aortic valve calcification and more tendency to BAV abnormalities. It is expected that TAVI products in China will adopt unique designs to address such physical conditions of Chinese patients.

Overseas Markets

In 2019, over 80% of the global TAVI procedures were completed in developed countries. In 2019, there were approximately 66,800 TAVI procedures performed in the U.S., approximately 6,800

TAVI procedures performed in Japan and approximately 52,100 performed in other developed countries. Among these countries, developed countries in Europe present significant opportunities for foreign medical device companies as these countries are regulated under the same EMA-administered regulatory framework where medical devices bearing the CE Mark can be marketed in these countries. In addition, foreign medical device manufacturers may use clinical trial data obtained in clinical trials that comply with the international standards to support the CE Mark application, which makes the registration pathway more efficient and cost-effective.

In addition, TAVI markets in developing countries are still under-penetrated but have high potential for future growth. In general, these countries do not require additional domestic clinical trials for medical devices that have already obtained marketing approval from developed countries or regions (such as the FDA approval and the CE Mark) and/or its country of origins. In 2019, there were approximately 20,400 TAVI procedures performed in developing countries excluding China which is expected to grow at a CAGR of 22.5% to approximately 68,700 in 2025.

COMPETITIVE LANDSCAPE

TAVI Market

As of the Latest Practicable Date, VitaFlow™ was one of the four domestically-developed TAVI products that had been approved for commercialization in China. In addition to VitaFlow™, VenusA-Valve and VenusA-Plus of Venus Medtech, J-Valve of Suzhou Jiecheng and SAPIEN 3 of Edwards Lifesciences had also been approved for commercialization in China. As of the same date, VitaFlow™ II was one of the three upgraded products under or beyond clinical trial stage in China. The following chart summarizes major TAVI products reaching clinical trial or commercialization stage in China.

Company	Product	Stage	Approval time[1]	Vascular Approach[2]	Expanding Mechanism[3]	Leaflet Material[4]	Profile	Retrievability	Outer Sealing Skirt	Motorized Handle	Price[5] RMB
MicroPort	VitaFlow™	Commercialized	2019.7	TF	SE	BP	16F,18F	×	√	√	196,000
	VitaFlow™ II	Registration in progress	NA	TF	SE	BP	NA	√	√	√	NA
启明医疗 VENUS MEDTECH	VenusA-Valve	Commercialized	2017.4	TF	SE	PP	16F,18F 19F,20F	×	×	×	248,000
	VenusA-Plus	Approved	2020.11	TF	SE	PP	NA	√	×	×	NA[6]
苏州杰成医疗	J-Valve	Commercialized	2017.4	TA	SE	PP	NA	×	×	×	260,000
Edwards	SAPIEN 3	Commercialized	2020.6	TF	BE	BP	14F,16F	×	√	×	Approximately 380,000
PEIJIA	TaurusOne	Registration in progress	NA	TF	SE	BP	18F	×	√	×	NA
	TaurusElite	Clinical trial	NA	TF	SE	BP	NA	√	√	×	NA

Notes:

1. The actual approval time is based on the NMPA announcements.
2. TF refers to transfemoral approach. TA refers to transapical approach.
3. SE refers to self-expanding mechanism. BE refers to balloon-expandable mechanism.
4. BP refers to bovine pericardium. PP refers to porcine pericardium.
5. The prices of VenusA-Valve, J-Valve and VitaFlow™ set forth herein are provided by Frost & Sullivan, based on the public wholesale tender prices of the relevant products in China as of the Latest Practicable Date. The prices of such products may be subject to changes, over which we do not have control. The price of SAPIEN 3 is mainly based on its global pricing and public information.

6. As VenusA-Plus has recently been approved by the NMPA in November 2020, as of the Latest Practicable Date the price of VenusA-Plus was not publicly available.

Source: Frost & Sullivan Report

The following table sets forth the clinical trial results of major TAVI products reaching clinical trial or commercialization stage in China.

Company	Product	30-days Mortality Rate[1]	30-days Major (Disabling) Stroke[1]	1-year Mortality Rate[1]	1-year Major (Disabling) Stroke[1]	1-year Moderate to Severe PVL Rate	1-year Major Vascular Complications	2-year Mortality Rate[1]	2-year Major (Disabling) Stroke[1]	3-year Mortality Rate[1]	3-year Major (Disabling) Stroke[1]
MicroPort	VitaFlow™	0.9%	0.0%	2.7%	0.0%	0.0%	2.7%	4.5%	0.0%	10.9%	1.8%
	VitaFlow™ II	5.0%	0.0%*	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
启明医疗 VENUS-MEDTECH	VenusA-Valve	5.0%	1.0%	5.9%	1.0%	4.2%	5.9%	8.9%	1.0%	12.9%	1.0%
	VenusA-Plus	4.8%	1.6%	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
苏州杰成医疗	J-Valve	4.7%	0.0%	5.6%	2.0%	1.1%	N/A	9.1%	2.0%	10.8%	N/A
Edwards	SAPIEN 3 (U.S. Trial)	2.2%	0.9%*	14.4%	2.4%*	2.7%	N/A	N/A	N/A	N/A	N/A
	SAPIEN 3 (China Trial)	0.0%	2.0%*	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
PEIJIA	TaurusOne	1.7%	NA	6.7%	N/A	1.0%	4.2%	N/A	N/A	N/A	N/A
	TaurusElite	N/A	NA	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

1. The data is from pivotal clinical trial of corresponding products and not head-to-head clinical results. VitaFlow™ (N=110), VitaFlow™ II (N=60), VenusA-Valve (N=101), VenusA-Plus(N=62), J-Valve (N=107), TaurusOne (N=120), SAPIEN 3 China Trial (N=50), U.S. Trial (N=583)

*: The data marked with * represent the incidences of disabling stroke.

Source: Frost & Sullivan Report

The efficacy, durability and operability of TAVI products are usually determined by the following key technologies:

- *Skirt design.* A better skirt design can optimize the sealing effect and effectively reduce PVL and regurgitation. PVL is one of the major complications post-TAVI procedures, which may lead to atrial fibrillation, pulmonary hypertension, or even heart failure.

- *Pericardium material.* Bovine pericardium and porcine pericardium are the most used pericardium materials. Bovine pericardium contains as much as two times collagen that porcine pericardium contains and provides a larger effective orifice area, which in turn reduces the damage to the valve caused by the blood flow. In addition, the bovine pericardium is generally thicker, has greater durability compared with porcine pericardium and is less likely to incur complications. As a result, bovine pericardium has been dominating the global TAVI market with over 55% market share and substantially the entire global SAVR market.

- *Delivery system.* Each TAVI product has been equipped with a delivery system controlled by either a motorized or manual handle. Motorized handles can concurrently deploy valve

and position guidewires. In addition, the motorized handle also makes the deployment of the valve easier to control, which will help shorten the learning curve for physicians.

TMV Market

For patients with severe MR, the standard treatment is mitral valve replacement or repair under extracorporeal circulation through open-chest surgery. However, due to the lack of effective treatment method and commercialized products as well as the inherent higher surgical risks attributable to the characteristics of mitral valve, in 2019, only less than 1% of the patients with MR received surgical treatment. The vast but underserved TMV market indicated significant growth potential and global TMV market is expected to increase to US$17.4 billion (or RMB117.0 billion) by 2030 and will eventually grow to three to four times of the TAVI market size.

Currently, there are only seven TMV repair or replacement products that received FDA approval or CE Mark, including six TMV repair products and one TMV replacement products. MitraClip, which was recently approved by the NMPA in June 2020, was the only TMV repair product that has been approved for commercialization in the United States, Europe and China. In January 2020, Tendyne TMV replacement product was approved by the EMA, becoming the first TMV replacement product worldwide that obtained marketing approval. The following table sets forth TMV repair or replacement product that received marketing approval in the U.S, Europe or China.

Marketed TMV Repair and Replacement Products

Product	Tendyne	MitraClip	CARILLON Mitral Contour System	NeoChord DS1000	Cardioband	PASCAL	MPAS Implant
							
FDA Approval	—	2013	—	—	—	—	—
CE Mark	2020	2008	2009	2013	2015	2019	2016
NMPA Approval	—	2020	—	—	—	—	—
Approach	Replacement (High or Extreme risk)	Edge to Edge Repair	Indirect Annuloplasty	Chordal Repair	Direct Annuloplasty	Edge to Edge Repair	Direct Annuloplasty
Access	Transapical	Transfemoral & Transseptal	Right internal jugular vein	Transapical	Transfemoral & Transseptal	Transfemoral & Transseptal	Transfemoral

Source: Frost & Sullivan Report

As global TMV market remains at an early development stage, there is a wide range of TMV repair or replacements under development. In China, most domestic companies are focusing on feasibility studies or animal studies for their TMV products and there is only one TMV repair product reaching clinical trial stage in China, namely ValveClamp from Hanyu Medical.