

INDUSTRY OVERVIEW

This section contains certain information and statistics relating to our industry which is derived from official government sources. In addition, this section and elsewhere in the document contain information extracted from a report prepared by Frost & Sullivan⁽¹⁾, commissioned by us for purposes of this document. However, the information derived from official government sources has not been independently verified by us, the Sole Sponsor, or any other party involved in the [REDACTED], and no representation is given as to its accuracy. Except as otherwise noted, all the data and forecast in this section are derived from the F&S Report. Accordingly, the information from official government sources contained here may not be accurate and should not be given undue reliance.

OVERVIEW OF STRUCTURAL HEART DISEASES

Cardiovascular disease, or heart disease, is a general term that describes heart abnormalities, including primarily coronary heart diseases, arrhythmia, and structural heart diseases. Structural heart disease includes primarily CHD, valvular disease, cardiomyopathy, and complications caused by other conditions, such as atrial fibrillation, which increases the risk of, among others, cardioembolic stroke and myocardial infarction.

CHD refers to the formation of the heart and blood vessels during embryonic development or abnormal development or failure to close the channels that should be automatically closed after birth, resulting in abnormalities in the solid structure or function of the blood vessels in the heart or thoracic cavity. CHD includes primarily ASD, VSD, and PDA. ASD refers to the remnant opening, or a defect, between the left and right atria resulting from the abnormal development, absorption and fusion of the atrial septum during embryonic development. It causes the blood in the left atrium to flow into the right atrium and right ventricle, and then flows to the pulmonary artery. VSD refers to the opening, or a defect between the left and right

⁽¹⁾ We commissioned Frost & Sullivan, a market research and consulting company, which is an independent third party, to conduct research and analysis of, and to produce a report on medical device market study of cardiovascular occluder and transcatheter valve therapies for the period from 2017 to 2030 (the “F&S Report”). The F&S Report has been prepared by Frost & Sullivan independent of the influence of our Group and other interested parties. We have agreed to pay Frost & Sullivan a total fee of RMB650,000 for the preparation and use of the F&S Report, and we believe that such fees are consistent with the market rate. Frost & Sullivan is a consulting firm founded in Hong Kong and provides professional industry consulting services across multiple industries. Frost & Sullivan’s services include industry consultancy services, commercial due diligence, and strategic consulting.

In compiling and preparing the report, Frost & Sullivan conducted both primary and secondary research using a variety of resources. Primary research involved interviewing key industry experts and leading industry participants. Secondary research involved analyzing data from various publicly available data sources, including but not limited to the National Bureau of Statistics, National Medical Products Administration, Food and Drug Association, National Health Commission of the PRC, the International Monetary Fund, World Health Organization. The market projections in the F&S Report are based on the following key assumptions: (1) the overall social, economic and political environment in China is expected to remain stable during the forecast period; (2) China’s economic and industrial development is likely to maintain a steady growth trend over the next decade; (3) related key industry drivers are likely to continue driving the growth of the medical device market in China during the forecast period, such as the increasing number of surgeries, growing acceptance of domestic products, supportive government programs and policies, increasing amount of research and development expenditures, increasing patient affordability; (4) the negative impact caused by COVID-19 outbreak in 2020, 2021 and 2022 on the industry is expected to be limited, taking into account the impact of the COVID-19 outbreak and estimating market growth for 2020, 2021 and 2022 in a conservative manner based on the industry and economic recovery in China since the second quarter of 2020; and (5) there is no extreme force majeure or industry regulation in which the market may be affected dramatically or fundamentally.

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ventricles resulting from incomplete development of the ventricular septum during the embryonic period. It causes blood to flow abnormally from the left ventricle to the right ventricle, and then to the pulmonary artery. PDA refers to a remnant opening of the normal blood vessel between the pulmonary artery and the aorta during the fetal period, which failed to be closed normally after birth. It causes the poorly oxygenated blood to flow in the wrong direction, which weakens the myocardium, leading to heart failure and other complications.

Cardioembolic stroke refers to a clinical syndrome in which cardiogenic emboli from the heart and aortic arch through blood circulation cause cerebral artery thrombosis and corresponding brain dysfunction. LAA is a small, ear-shaped sac in the muscle wall of the left atrium. Blood is likely to clot in the LAA to form thrombus in patients with atrial fibrillation. LAA occlusion procedures prevent the formation and breaking off of thrombus, which serves to prevent cardioembolic stroke. PFO is a small hole between the right and the left atrium. Every baby is born with a PFO, which usually closes very soon after birth. When a PFO fails to close, blood may bypass the lung and go directly from the right atrium to the left atrium. This may cause thrombus in the venous system and right atrium to flow into the left heart system from the right heart through the open foramen ovale and reach the brain, which leads to cerebral venous thrombosis, causing stroke.

Valvular disease is caused by valvular stenosis or valvular insufficiency in one of the four heart valves (i.e., aortic valve, pulmonary valve, mitral valve, and tricuspid valve) that leads to heart disease. The aortic valve governs blood flow between the heart and the aorta, and thereby the blood vessels to the rest of the body. The pulmonary valve controls the flow of blood from the heart to the lungs. The mitral and tricuspid valves control the flow of blood between the atria and the ventricles. Valvular disease includes primarily aortic valve disease, mitral valve disease, and tricuspid valve disease. Aortic valve disease is a condition in which the valve between the main pumping chamber of one's heart, the left ventricle, and the main artery to the body, the aorta, does not work properly. Major types of aortic valve disease include aortic stenosis and aortic regurgitation.

Mitral valve disease is a condition in which the mitral valve, located between the heart's left upper chamber and the left lower chamber, does not close properly or open completely. Major types of mitral valve disease include mitral stenosis and mitral regurgitation, which may lead to complications such as pulmonary hypertension, atrial fibrillation, and thromboembolism. Tricuspid valve disease is a condition in which the valve between the right ventricle and right atrium does not close properly. Major types of tricuspid valve diseases include tricuspid stenosis and tricuspid regurgitation, which may lead to symptoms such as shortness of breath, atrial fibrillation and atrial flutter. Among the different types of valvular diseases, aortic valve disease and mitral valve disease are most common.

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GLOBAL AND CHINA’S INTERVENTIONAL MEDICAL DEVICE MARKETS TARGETING STRUCTURAL HEART DISEASES

Overview

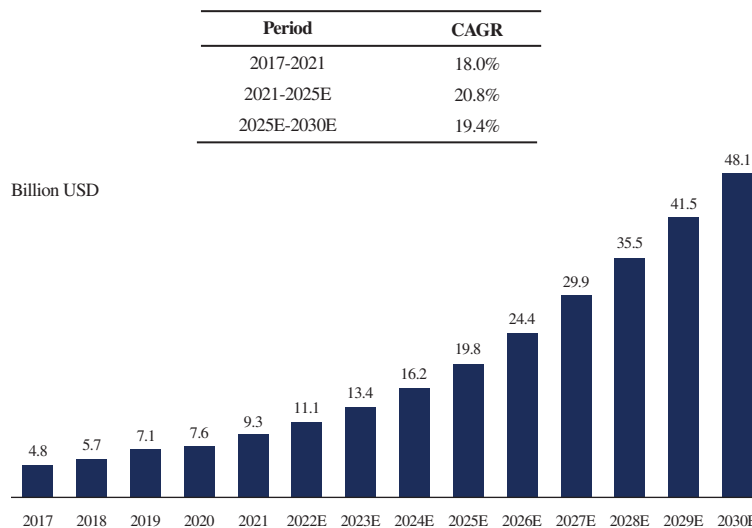
Interventional therapy targeting structural heart diseases is a technique that enters the heart cavity or blood vessel through a blood vessel puncture route for structural heart disease diagnosis or treatment. Medical practitioners use puncture needles, catheters, and other interventional devices to introduce specific devices into human body lesions by natural orifices or small incision made from minimally invasive procedures.

Eligible patients for interventional therapy targeting structural heart diseases primarily include surgery inoperable patients, patients with no improvement after drug treatment, or patients without significant improvement after surgery. Globally, the number of eligible patients for interventional therapy targeting structural heart diseases increased from approximately 25.9 million in 2017 to approximately 29.4 million in 2021, and is expected to reach 34.2 million in 2025. In China, the number of eligible patients for interventional therapy targeting structural heart diseases increased from approximately 4.8 million in 2017 to approximately 5.3 million in 2021, and is expected to reach 6.0 million in 2025. Driven by the large patient pool, the rising disposable income per capita, and the supportive regulatory framework, it is expected that China will experience a significant growth in interventional therapy targeting structural heart diseases in the future.

Market Size

The global interventional medical device market targeting structural heart diseases has experienced rapid growth from US\$4.8 billion in 2017 to US\$9.3 billion in 2021 at a CAGR of 18.0%, in terms of sales revenue, and is expected to reach US\$19.8 billion in 2025 at a CAGR of 20.8% from 2021 to 2025. The following chart sets forth the historical and forecasted growth of the global interventional medical device market targeting structural heart diseases.

Global Interventional Medical Device Market Targeting Structural Heart Diseases, 2017-2030E

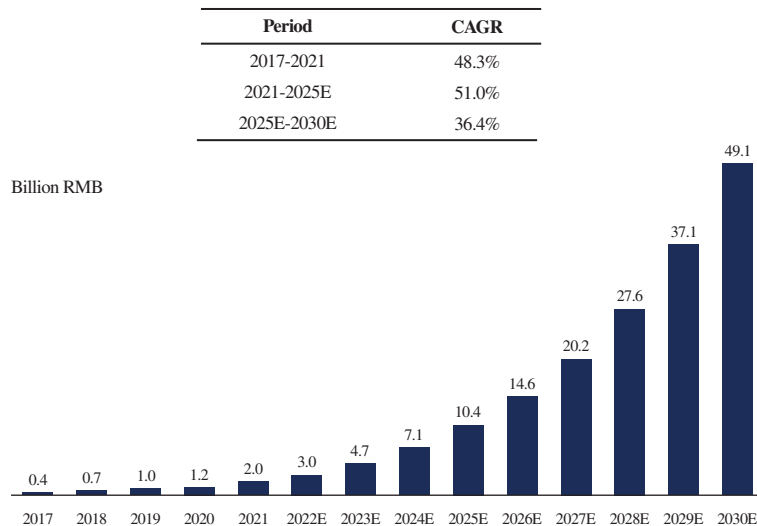


Source: F&S Report

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In China, the number of eligible patients for interventional therapy targeting structural heart diseases increased from approximately 4.8 million in 2017 to approximately 5.3 million in 2021 and is expected to reach approximately 6.0 million in 2025. The market size of China’s interventional medical device market targeting structural heart diseases grew from RMB0.4 billion in 2017 to RMB2.0 billion in 2021 at a CAGR of 48.3%, and is expected to reach RMB10.4 billion in 2025 at a CAGR of 51.0% from 2021 to 2025. The following chart sets forth the historical and forecasted growth of China’s interventional medical device market targeting structural heart diseases.

China’s Interventional Medical Device Market Targeting Structural Heart Diseases, 2017-2030E



Source: F&S Report

Market Drivers and Trends

Key growth drivers and trends of global and China’s interventional medical device markets targeting structural heart diseases include the following:

- *Increasing substitution of open surgeries with interventional therapies.* Compared to traditional open surgeries which require large cuts in the skin, medical practitioners can perform interventional therapies with reduced or no incision. Patients will experience less pain, scarring and complications, lowered risk of infection, and shortened hospital stays and recovery time.
- *Growing acceptance of domestic products in China.* Because domestic players continue to increase their investment in research and development and manufacturing, high quality and cost-effective domestic interventional medical devices have gained increasing recognition and growing competitiveness against imported products, which we believe have contributed and will continue to contribute to the market acceptance of our products.

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- *Product upgrades and innovation.* Advancement in material science, PCI technology, and clinical practices drive innovative interventional therapies. Leveraging PCI technology, biodegradable stents can achieve “intervention without implantation” and contribute to vascular reconstruction with better long-term safety.
- *AI technologies empower interventional therapies.* Under the governmental support and the scientific innovation of the AI technology, the innovative commercialized applications of vascular AI have emerged, improving existing interventional therapies and indirectly boosting the interventional medical devices market.

MAIN PRODUCT CATEGORIES OF INTERVENTIONAL MEDICAL DEVICE MARKET TARGETING STRUCTURAL HEART DISEASES

The interventional medical device market targeting structural heart diseases consists primarily of three major fields of application, i.e., CHD, cardioembolic stroke, and valvular diseases. CHD occluder products include primarily ASD occluder, VSD occluder, and PDA occluder. Cardioembolic stroke occluder products include primarily PFO occluder and LAA occluder. Heart valve products to treat valvular diseases include primarily aortic valve products and mitral valve products.

CHD Occluder Products

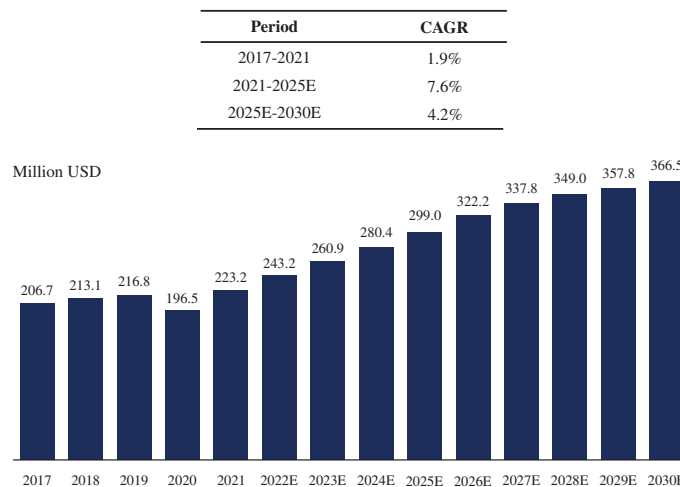
Overview

CHD interventional occlusion is a method of puncturing the peripheral blood vessels and pushing the delivery catheter and occluder to the corresponding part of the congenital heart development defect with the assistance of X-ray fluoroscopy guidance and bedside cardiac color Doppler ultrasound. It is a minimally invasive treatment technology for cardiovascular blocking for treating ASD, VSD, and PDA.

Market Size

The following chart sets forth the historical and projected sales revenue of the global CHD occluder products market for the periods indicated.

Global CHD Occluder Products Market, 2017-2030E



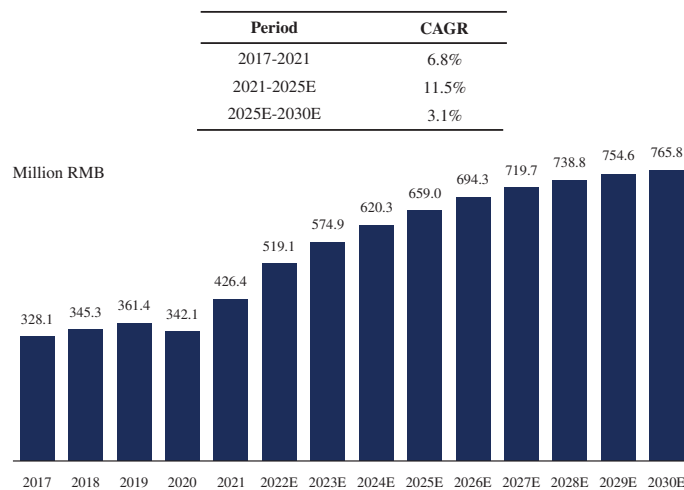
Source: F&S Report

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Note: The size of the global CHD occluder products market only includes the market size of three main CHD occluders, namely ASD occluder, VSD occluder and PDA occluder.

The following chart sets forth the historical and projected sales revenue of China’s CHD occluder products market for the periods indicated. The decline of the market size in 2020 was primarily as a result of the reduced demand among hospitals for medical devices as a result of the decrease of operations, as most of the hospitals devoted their resources primarily to dealing with COVID-19 in the first half of 2020. The market size increased in 2021 as a result of the increased demand for medical devices along with the effective containment of COVID-19 and the launch of an increasing number of CHD occluder products. The incidence of CHD in China was 133,400 in 2021 and is expected to reach 144,800 in 2030; and the global incidence of CHD was 1.7 million in 2021 and is expected to remain relatively stable in 2030.

China’s CHD Occluder Products Market, 2017-2030E



Source: F&S Report

Note: The size of China’s CHD occluder products market includes the market size of three main CHD occluders, namely ASD occluder, VSD occluder and PDA occluder, and the market size of the related procedural accessories.

Market Driver and Future Trends

Key growth driver and future trends of global and China’s CHD occluder products markets include the following:

- *Supportive medical insurance policy in China.* CHD patients are mainly in the underdeveloped central and western regions in China. At present, the reimbursement ratio of the new rural cooperative medical insurance for major illnesses is different from the reimbursement ratio of large cities in the southeast coastal area, which is generally higher than other regions. The Chinese government seeks to increase the reimbursement ratio from the current level and scope; therefore, we expect CHD occluder products will become more affordable for patients in central and western regions in China.

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- *High market potential in China.* At present, there are approximately 150,000 newborns with CHD in China each year. However, compared with the high treatment rate of CHD in Europe and the United States, the current treatment of CHD patients in China is low, and so is the penetration rate of CHD occluder products in China. The domestic market for CHD occluder devices is expected to proliferate in the future, which we believe will provide further demand for our CHD occluder products.
- *Technology development.* The treatment for CHD has a remarkable change in the past decade due to the evolution of the medical device. Interventional therapy has become the primary treatment option for CHD patients because such therapy has better outcomes and fewer complications than other treatment options.
- *Increasing substitution of open surgeries with interventional therapies.* Compared to traditional open surgeries which require large cuts in the skin, medical practitioners can perform interventional therapies with reduced or no incision. CHD patients will have reduced associated pain, scarring and complications, lowered risk of infection, and shortened hospital stays and recovery time.

Competitive Landscape

In China, domestic CHD manufacturers dominated the market with market share of approximately 91.5% in 2021, with the remaining approximately 8.5% occupied by international CHD manufacturers. The following charts set forth the top five players in China’s occluder products market, in terms of revenue recognized for the sales in China in 2021. We are the largest manufacturer of CHD occluder products and the related procedural accessories in China, and we believe that we will continue to remain competitive in the market, leveraging our broad product portfolio of marketed and pipeline products.

Top Five Players in China’s CHD Occluder Products Market, 2021

Ranking	Company	Sales revenue	Market share by sales revenue
		<i>(RMB million)</i>	
1	Our Company	162.2	38.0%
2	Company A	146.0	34.2%
3	Company B	52.9	12.4%
4	Company C	36.4	8.5%
5	Company D	9.1	2.1%
	Subtotal	406.5	95.3%

Source: F&S Report

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Cardioembolic Stroke Occluder Products

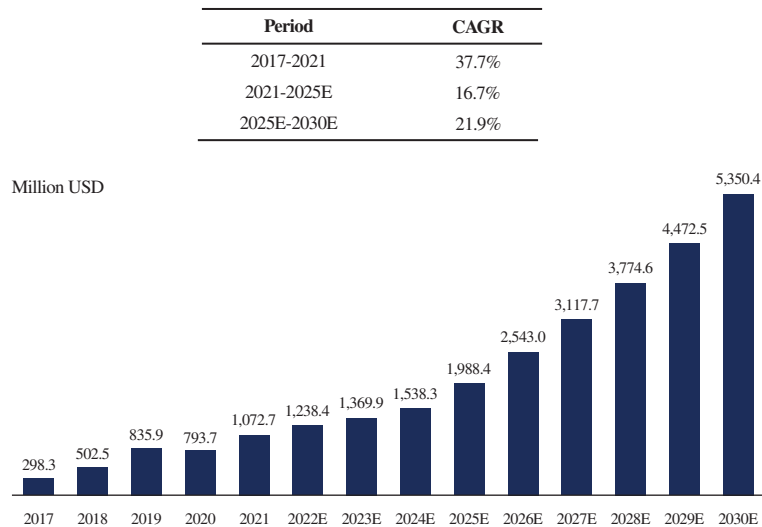
Overview

Interventional occlusion is a method for the prevention of cardioembolic stroke and related symptoms, including migraine, peripheral arterial embolism, and decompression sickness. Cardioembolic stroke occluder products primarily include PFO and LAA occluder products.

Market Size

The following chart sets forth the historical and projected sales revenue of the global cardioembolic stroke occluder products market for the periods indicated. The decline of the market size in 2020 was primarily due to the COVID-19 impact.

Global Cardioembolic Stroke Occluder Products Market, 2017-2030E



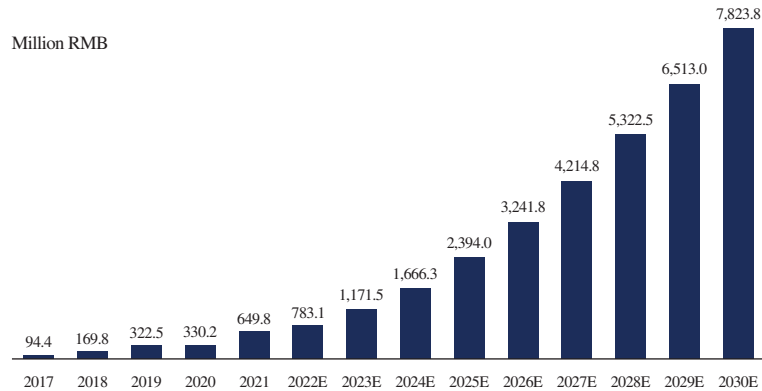
Source: F&S Report

The prevalence of cardioembolic stroke in China was 4.5 million in 2021 and is expected to reach 5.7 million in 2030; and the global prevalence of cardioembolic stroke was 19.7 million in 2021 and is expected to reach 29.6 million in 2030. The following chart sets forth the historical and projected sales revenue of China’s cardioembolic stroke occluder products market for the periods indicated.

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China’s Cardioembolic Stroke Occluder Products Market, 2017-2030E

Period	CAGR
2017-2021	62.0%
2021-2025E	38.5%
2025E-2030E	26.7%



Source: F&S Report

Market Driver and Future Trends

Key growth driver and future trends of global and China’s cardioembolic stroke occluder products markets include the following:

- *Growing demand in China.* The number of PFO occlusion procedures in China is increasing rapidly. As the evidence for migraine and paradoxical embolism becomes more apparent with the PFO occlusion, the demand for PFO occluder products is expected to grow. PFO occlusion procedures are minimally invasive, which offer an option for patients with other severe symptoms and other complications.
- *PFO occluder products will become biodegradable in the future.* Compared with metal implants, biodegradable PFO occluder products can degrade over time into carbon dioxide and water to provide better long-term safety. Accordingly, biodegradable PFO occluder products will become popular in the industry, which we believe will contribute to the market acceptance of our biodegradable PFO occluder product upon commercialization.
- *Increasing substitution of open surgeries with interventional therapies.* Compared to traditional open surgeries which require large cuts in the skin, medical practitioners can perform interventional therapies targeting structural heart diseases with reduced or no incision. Cardioembolic stroke patients will have reduced pain, scarring and complications, lowered risk of infection, and shortened hospital stays and recovery time.

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- Poor adherence to medication.* Atrial fibrillation is the most common type of sustained cardiac arrhythmia and a significant risk factor for stroke. Gold standard stroke prevention is lifelong anticoagulation, which is not suitable for all patients. Overall, 90% and 57% of thrombi found in non-valvular and valvular atrial fibrillation patients, respectively, are in the LAA, making it a target for stroke prevention. LAA occlusion devices are a mechanical alternative to oral anticoagulation.

PFO Occluder

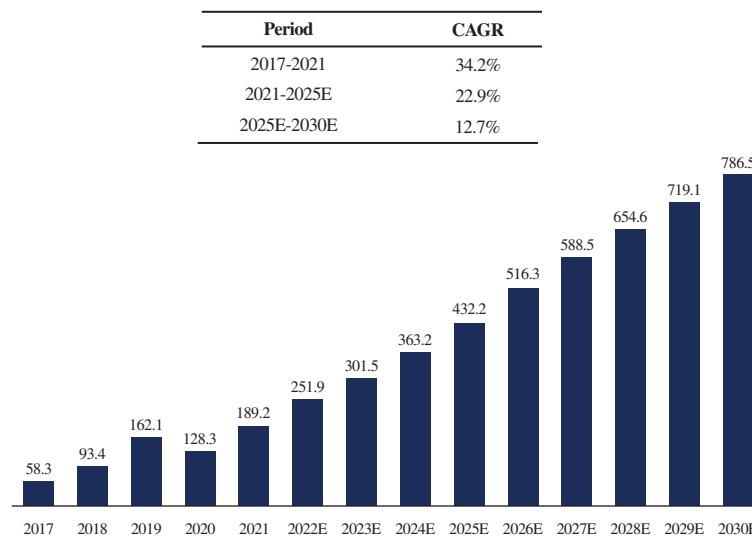
Overview

PFO occluder is a medical device that is delivered along the blood vessel to the patient’s PFO. A medical practitioner implants the PFO occluder into the patient’s PFO through a catheter from a small incision in the patient’s thigh groin. Once a medical practitioner confirms that the position is correct, the PFO occluder is opened, expands and forms on both sides of the interatrial septum, and releases the occluder.

Market Size

The following chart sets forth the historical and projected sales revenue of the global PFO occluder products market for the periods indicated. The decline of the market size in 2020 was primarily due to the COVID-19 impact.

Global PFO Occluder Products Market, 2017-2030E

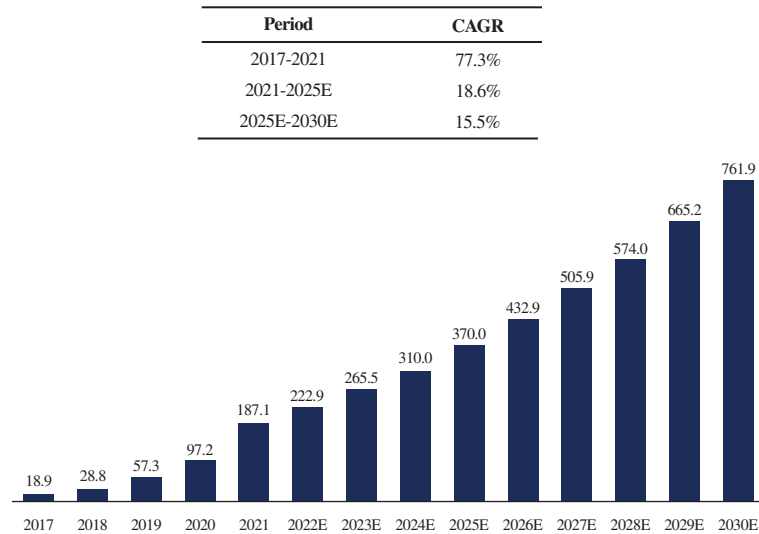


Source: F&S Report

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In 2021, the penetration rate of PFO occluder products in China was approximately 42.4%. The penetration rate of PFO occluder products in China is expected to grow to 59.9% by 2025. The following chart sets forth the historical and projected sales revenue of China’s PFO occluder products market for the periods indicated. The decline of the market size in 2020 was primarily due to the COVID-19 impact.

China’s PFO Occluder Products Market, 2017-2030E



Source: F&S Report

Competitive Landscape

PFO occluder therapy is still at an emerging stage, with only four players, including those with product candidates in the clinical trial stage, in China’s PFO occluder products market and only eight players in global PFO occluder products market with commercialized products as of the Latest Practicable Date. We had obtained one CE Mark for our PFO occluder product as of the Latest Practicable Date, and we expect to obtain the NMPA approval for our biodegradable PFO occluder product in the third quarter of 2023.

The following chart sets forth the existing players in China’s PFO occluder products market with commercialized products or product candidates in the clinical trial stage as of the Latest Practicable Date.

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Existing Players in China’s PFO Occluder Products Market

Company	Product	Registration Date/ Current Stage	Materials
AGA Medical Corporation	AMPLATZER PFO Occluder	NMPA approval in 2016	Alloy
Starway Medical Technology Inc.	PFO Occluder	NMPA approval in 2017	Alloy
Our Company	MemoSorb	Registration preparation stage	Fully biodegradable materials
Shanghai Mallow Medical Instrument Co., Ltd.	PFO Occluder	Clinical trial stage	Biodegradable materials

Source: F&S Report

LAA Occluder

Overview

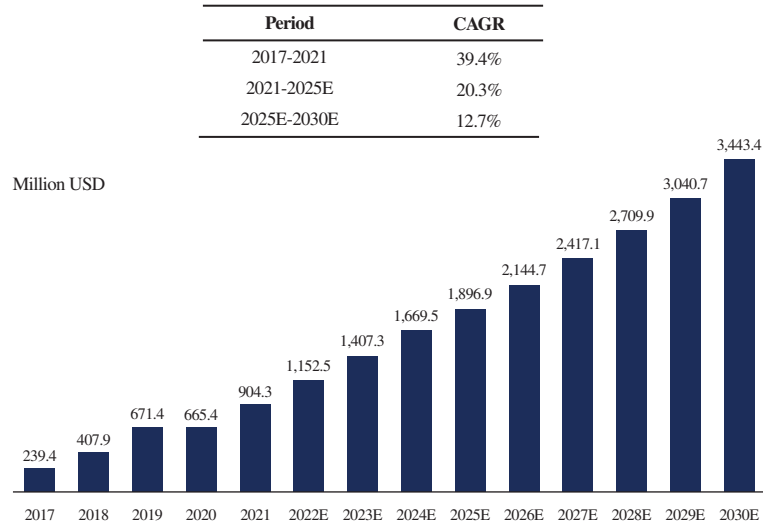
LAA occluder is a medical device that blocks LAA to prevent the formation and breaking off of thrombus, thereby preventing cardioembolic stroke. Patients may use LAA occlusion when there is no improvement after the drug treatment. For patients who have a high risk of bleeding and embolism, and are not suitable for long-term oral anticoagulant therapy, implantation of the LAA occluder is a better option for them. Through interventional therapy, a medical practitioner implants the LAA occluder into the patient’s LAA to treat the cardioembolic stroke.

Market Size

The following chart sets forth the historical and projected sales revenue of the global LAA occluder products market for the periods indicated.

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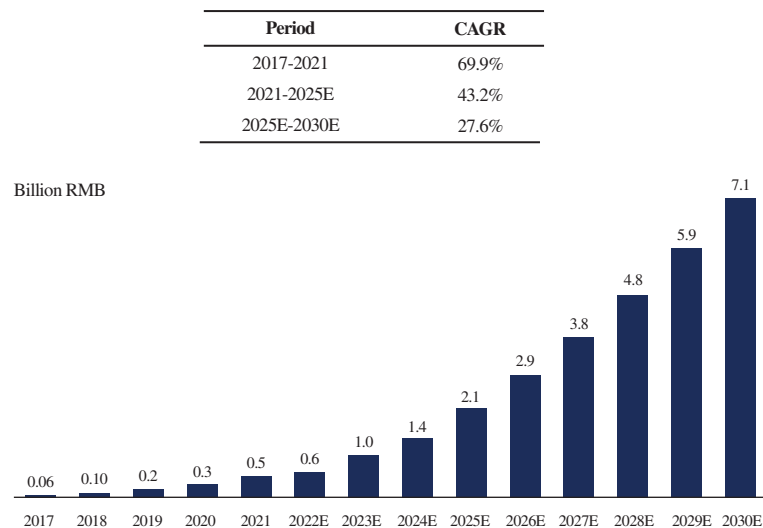
Global LAA Occluder Products Market, 2017-2030E



Source: F&S Report

In 2021, the penetration rate of LAA occluder products in China was approximately 5.9%, as compared to 44.9% in the United States and 14.6% in Europe, respectively. The penetration rate of LAA occluder products in China is expected to grow to 19.4% by 2025. The following chart sets forth the historical and projected sales revenue of China’s LAA occluder products market for the periods indicated.

China’s LAA Occluder Products Market, 2017-2030E



Source: F&S Report

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Competitive Landscape

LAA occluder therapy is still at an emerging stage, with only seven major players in China’s LAA occluder products market and four major players in global LAA occluder products market with commercialized products as of the Latest Practicable Date. We had obtained one NMPA registration certificate for our LAA occluder product as of the Latest Practicable Date, and our biodegradable LAA occluder product candidate was in the stage of type inspection.

The following chart sets forth the existing players in China’s LAA occluder products market with commercialized products as of the Latest Practicable Date.

Existing Players in China’s LAA Occluder Products Market

Company	Product	Registration Date	Materials
Our Company	MemoLefort	NMPA approval in 2020	Alloy
Shanghai Push Medical Device Co., Ltd.	LACbes	NMPA approval in 2019	Alloy
Lifetech Scientific (Shenzhen) Co., Ltd.	LAmbre	NMPA approval in 2017	Alloy
	LAXible	NMPA approval in 2021	Alloy
St. Jude Medical, Inc.	AMPLATZER Amulet	NMPA approval in 2015	Alloy
Boston Scientific Corporation	WATCHMAN	NMPA approval in 2013	Alloy
Shanghai HeartCare Medical Technology Co., Ltd.	Laager	NMPA approval in 2022	Alloy
Shenzhen Salubris Pharmaceuticals Co., Ltd.	LAMax	NMPA approval in 2022	Alloy

Source: F&S Report

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Heart Valve Products

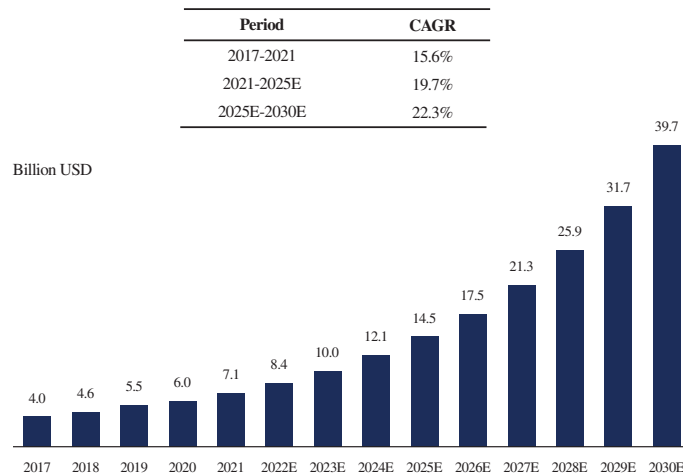
Overview

Heart valve products are medical devices implanted through interventional means, which primarily include aortic valve products and mitral valve products.

Market Size

The following chart sets forth the historical and projected sales revenue of the global valvular disease interventional device market for the periods indicated.

Global Valvular Disease Interventional Device Market, 2017-2030E

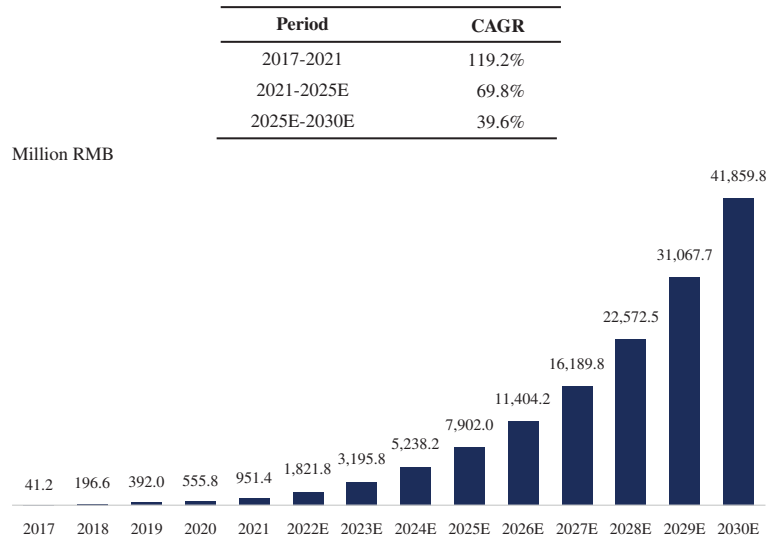


Source: F&S Report

The prevalence of valvular diseases in China was 37.7 million in 2021 and is expected to reach 42.7 million in 2030; and the global prevalence of valvular diseases was 220.9 million in 2021 and is expected to reach 246.7 million in 2030. The penetration rate of valvular disease interventional devices is significantly under-penetrated due to the insufficient number of qualified hospitals with experienced physicians. The market size of China’s valvular disease interventional device market is expected to increase from RMB1.0 billion in 2021 to RMB7.9 billion in 2025 at a CAGR of 69.8%. By 2025, the number of TMVr operations to be performed is expected to reach approximately 9,970 in China with a penetration rate of 0.08% for the TMVr operation. The following chart sets forth the historical and projected sales revenue of the China’s valvular disease interventional device market for the periods indicated.

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China’s Valvular Disease Interventional Device Market, 2017-2030E



Source: F&S Report

Aortic Valve Products

Overview

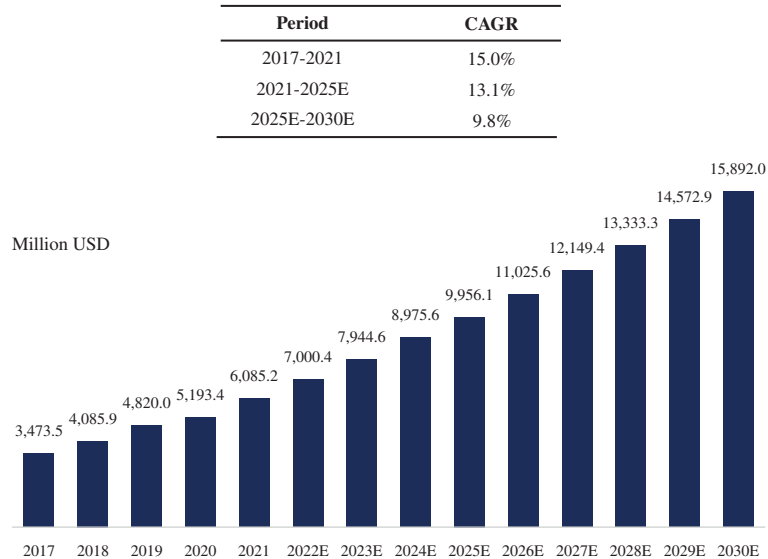
Aortic valve products primarily include TAVR system. TAVR technique implants a prosthetic valve through a vascular path to treat aortic stenosis and aortic regurgitation. TAVR technique has the advantages of small trauma and short postoperative recovery periods, which makes it suitable for patients with severe aortic stenosis or aortic regurgitation who cannot tolerate surgical aortic valve replacement.

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Market Size

The following chart sets forth the historical and projected sales revenue of the global TAVR market for the periods indicated.

Global TAVR Market, 2017-2030E



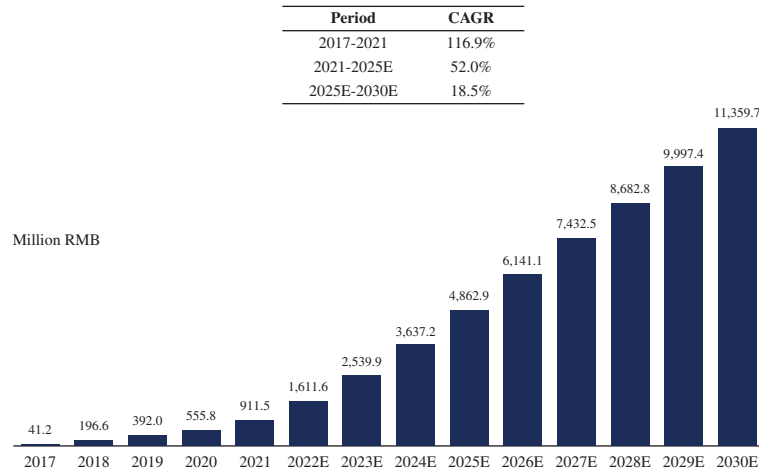
Source: F&S Report

The prevalence of aortic stenosis in China was 4.5 million in 2021 and is expected to reach 5.2 million in 2030; and the global prevalence of aortic stenosis was 20.4 million in 2021 and is expected to reach 23.9 million in 2030. The prevalence of aortic regurgitation in China was 4.0 million in 2021 and is expected to reach 4.6 million in 2030; and the global prevalence of aortic regurgitation was 27.5 million in 2021 and is expected to reach 31.6 million in 2030. Due to the insufficient number of qualified hospitals with experienced physicians, the TAVR market in China is significantly under-penetrated with only 0.8% of eligible patients treated by TAVR procedures in 2021, as compared to 4.3% globally. The number of TAVR operations to be performed in China is expected to grow from 6,600 in 2021 to 43,000 in 2025, with a CAGR of 59.6%.

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The following chart sets forth the historical and projected sales revenue of China’s TAVR market for the periods indicated.

China’s TAVR Market, 2017-2030E



Source: F&S Report

Competitive Landscape

TAVR market is still at an emerging stage, and there were only six major players in China’s TAVR market with only nine commercialized TAVR systems as of the Latest Practicable Date. Our TAVR system was in the clinical trial stage as of the Latest Practicable Date, and we expect to submit application to the NMPA in the fourth quarter of 2023.

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The following chart sets forth the existing players in China’s TAVR market with commercialized products as of the Latest Practicable Date.

Existing Players in China’s TAVR Market

Company	Product	Registration Date	Access
MicroPort CardioFlow Medtech Corporation	VitaFlow	NMPA approval in 2019	Transfemoral
	VitaFlow Liberty™	NMPA approval in 2021	Transfemoral
Venus Medtech Corporation	VenusA-Valve	NMPA approval in 2017	Transfemoral
	VenusA-Plus	NMPA approval in 2020	Transfemoral
Peijia Medical Limited	TaurusOne	NMPA approval in 2021	Transfemoral
	TaurusElite	NMPA approval in 2021	Transfemoral
Suzhou JieCheng Medical Technology Co., Ltd.	J-Valve	NMPA approval in 2017	Transapical
Edwards Lifesciences Corporation	SAPIEN 3	NMPA approval in 2020	Transfemoral
Medtronic plc	Evolut Pro	NMPA approval in 2021	Transfemoral

Source: F&S Report

Market Drivers and Future Trends

Key growth drivers and future trends of global and China’s TAVR market include the following:

- Underserved demand.* The prevalence of aortic valve disease increases with age. Given China’s large population base, the number of high-risk aortic stenosis patients in China is enormous. For elderly patients with comorbidities, traditional surgical atrial valve replacement has a higher risk, and the post-operative recovery can be relatively slow; therefore, it is difficult to obtain effective treatment for them. The emergence of TAVR provides an alternative option for such patients with lower risk and more rapid recovery. Therefore, it is foreseeable that TAVR systems will gain market prevalence, which we believe will contribute to the market acceptance of our TAVR system upon commercialization.

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- *Increasing TAVR applications.* As a relatively new and refined operation, TAVR has stringent requirements for medical equipment, personnel training and technical operation. The 2020 Version of Consensus of Chinese Experts on TAVR (經導管主動脈瓣置換術中國專家共識(2020更新版)) was released on May 30, 2020 by the 14th Eastern Conference of Cardiology Forum (第十四屆東方心臟病學會議結構論壇) to promote the technical training and talent cultivation for the development of TAVR in China. In 2021, more than 170 hospitals in China carried out more than 6,000 TAVR operations, with accelerating growth rate.
- *Regulatory support.* In 2016, the State Council issued the Health and Wellness Plan in Thirteenth Five-year (“十三五”衛生與健康規劃) to promote the development of medical equipment and support the improvement of the industry-wide capacity of medical equipment and application. In 2016, NMPA, NDRC and four other ministries released the Guidelines of Plan for Development of the Pharmaceutical Industry (醫藥工業發展規劃指南) to encourage innovative medical device research and development and commercialization. These government policies will sustain the further development of the TAVR market.

Mitral Valve Products

Overview

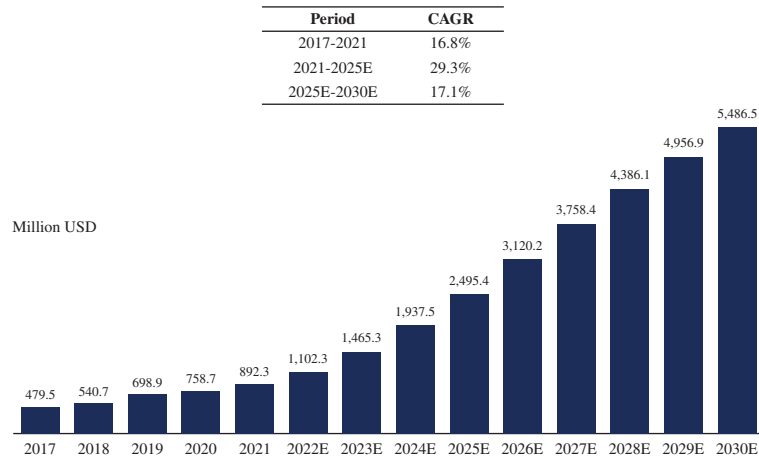
Mitral valve products primarily include the TMVCRS, the TMVr-A system, and the TMVr-F system. There are two different techniques used in mitral valve clip repair, i.e., TMVr-A and TMVr-F. TMVr market consists of (1) medical devices with application of TMVr-A technique, primarily including TMVr-A system and TMVCRS, and (2) medical devices with application of TMVr-F technique, primarily including TMVr-F system. TMVCRS is a transapical artificial chordal repair system targeting mitral regurgitation. TMVr products provide a minimally invasive option for treating the most common form of mitral regurgitation for people who cannot undergo open-chest surgery. Medical practitioners implant the product via a transcatheter technique and involve clipping together the anterior and posterior mitral valve leaflets. Compared to open-chest surgery, patients who received less invasive mitral valve products need fewer blood transfusions and ventilation days.

INDUSTRY OVERVIEW

Market Size

The following chart sets forth the historical and projected sales revenue of the global TMVr market for the periods indicated.

Global TMVr Market, 2017-2030E



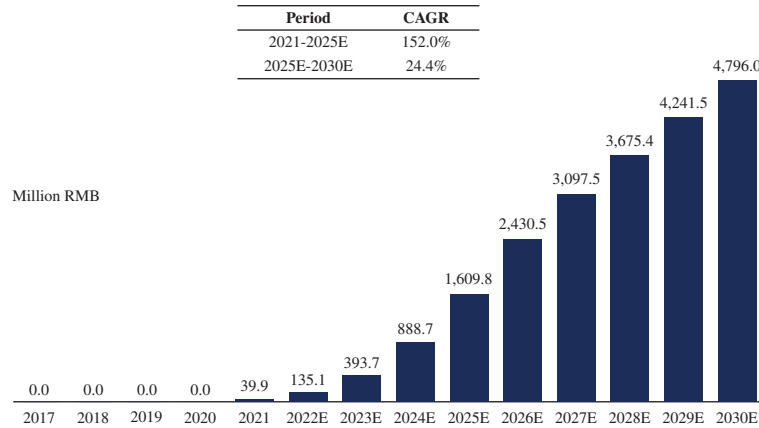
Source: F&S Report

The prevalence of mitral stenosis in China was 6.0 million in 2021 and is expected to reach 7.4 million in 2030; and the global prevalence of mitral stenosis was 16.9 million in 2021 and is expected to reach 20.2 million in 2030. The prevalence of mitral regurgitation in China was 11.1 million in 2021 and is expected to reach 13.4 million in 2030; and the global prevalence of mitral regurgitation was 99.9 million in 2021 and is expected to reach 122.0 million in 2030. The number of TMVr operations to be performed and the penetration rate of TMVr operations in China is expected to grow from approximately 190 and 0.002% in 2021 to approximately 9,970 and 0.08% by 2025, respectively.

INDUSTRY OVERVIEW

The following chart sets forth the projected sales revenue of China’s TMVr market for the periods indicated.

China’s TMVr Market, 2017-2030E



Source: F&S Report

Competitive Landscape

TMVr market is still at an emerging stage, and in 2021, there were 14 major players in China’s TMVr market, including us, with no commercialized products as of the end of 2021. Only one of such manufacturers had commercialized its TMVr device as of the Latest Practicable Date. In 2021, there were 17 major players in global TMVr market, among which only five manufacturers had commercialized their TMVr products as of the Latest Practicable Date. Our TMVCRS was at the clinical trial stage as of the Latest Practicable Date. We plan to submit registration application to the NMPA in the third quarter of 2024. As of the Latest Practicable Date, our TMVr-A system was at the clinical trial stage. We plan to submit registration application to the NMPA in the fourth quarter of 2023. Our TMVr-F system was in the type inspection stage as of the Latest Practicable Date.

INDUSTRY OVERVIEW

The following chart sets forth the existing players in China’s TMVr market with products under clinical trial stage as of the Latest Practicable Date.

Existing Players in China’s TMVr Market

Intended Use	Company	Product	Technique	Access
Repair	Hanyu Medical	ValveClamp	Edge-to-edge repair	Transapical
		ValveClasp	Edge-to-edge repair	Transfemoral
	Valgen Medtech	MitralStitch®	Mainly chordal implantation	Transapical
		DragonFly™	Edge-to-edge repair	Transfemoral
	SHSMA (Lepu Scientech)	Memoclip	Edge-to-edge repair	Transapical
	Med-zenith	E-chord™	Chordae tendineae repair	Transapical
	Dawneo Medical	NeoNova	Edge-to-edge repair	Transfemoral
	Shenqi Medical	Qilin™ System	Edge-to-edge repair	Transfemoral
		SQ-Kyrin	Edge-to-edge repair	NA
	NewMed Medical	Valveclip-M™	Edge-to-edge repair	Transfemoral
	KOKA Lifesciences	LIFECLIP®	Edge-to-edge repair	Transapical
		KokaClip®	Edge-to-edge repair	Transfemoral
	Lepu Scientech	TMVCRs	Chordae tendineae repair/ Edge-to-edge repair	Transapical
		TMVr-A	Edge-to-edge repair	Transapical
	Enlight Medical	NovoClasp	Edge-to-edge repair	Transfemoral & Transseptal
	HeartCare Medical	Clip2Edge®	Edge-to-edge repair	Transfemoral & Transseptal
	MVRx	ARTO	Indirect annuloplasty	Transseptal
Neochord	NeoChord DS1000	Chordae tendineae repair	Transapical	
Valcare Medical Ltd	Amend	Chordae tendineae repair/ Edge-to-edge repair	Transapical/ Transseptal	

Source: F&S Report

INDUSTRY OVERVIEW

The following chart sets forth the existing players in global TMVr market with commercialized products as of the Latest Practicable Date.

Existing Players in Global TMVr Market

Company	Product	Registration Date	Access
Abbott Laboratories	MitraClip	CE Mark in 2008	Transfemoral/Transseptal
		FDA approval in 2013	
		NMPA approval in 2020	
	Tendyne	CE Mark in 2020	Transapical
Cardiac Dimensions, Inc.	CARILLON Mitral Contour System	CE Mark in 2009	Right internal jugular vein
NeoChord, Inc.	NeoChord DS1000	CE Mark in 2013	Transapical
Edwards Lifesciences Corporation	Cardioband	CE Mark in 2015	Transfemoral/Transseptal
	PASCAL	CE Mark in 2019	Transfemoral/Transseptal
Mitralign, Inc.	MPAS Implant	CE Mark in 2016	Transfemoral

Source: F&S Report

Market Drivers and Future Trends

Key growth drivers and future trends of global and China’s TMVr market include the following:

- *Underserved demand.* Mitral valve diseases have the highest prevalence in China among all valvular diseases, and the prevalence continues to rise each year due to population aging. Mitral regurgitation is the most common mitral valve disease, and approximately 40% of the patients with mitral regurgitation are not eligible for surgery due to their elder age, impaired heart function, and numerous complications. As a minimally invasive and safer option, the TMVr procedure meet the increasing demands among patients with mitral regurgitation and other mitral valve diseases, which we believe will contribute to the market acceptance of our TMVr systems upon commercialization.
- *Advancement in disease evaluation technique.* Recent progresses have been made in echocardiography that helps to speed workflow, improve image quality, and improve valve assessments, by depicting the defective valves in structural heart diseases. Such improvement will optimize structural heart evaluations and facilitate the decision making for treating mitral valve disease, revealing more patients eligible for TMVr procedures.
- *Regulatory support.* By promoting the research and development and commercialization for innovative medical devices, government policies, such as the Health and Wellness Plan in Thirteenth Five-year (“十三五”衛生與健康規劃) and the Guidelines of Plan for Development of the Pharmaceutical Industry (醫藥工業發展規劃指南), will sustain the further development of the TMVr market.